



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Licensing Committee Report

Clarence Hiura, Chair
Ruth Conroy, Member
John Tilley, Member
Richard Benson, Member

Report of December 3, 2003

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy approve the proposed statewide protocol for emergency contraception with the request that the board consider modifying the protocol to allow furnishing up to 5 days after unprotected sex and to allow a single dose administration of Plan B.

Discussion

Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the Board of Pharmacy and the Medical Board of California. Prior legislation (Senate Bill 1196, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber.

The draft protocol synthesizes elements from protocols submitted by the Pharmacy Access Partnership and the American College of Obstetricians and Gynecologists. Staff also reviewed protocols from the states of New Mexico and Washington and a sample protocol employed by pharmacists under the existing protocol requirements. **(Attachment A)**

The draft protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490. Both the Board of Pharmacy and the Medical Board of California must approve the protocol. The Medical Board of California is awaiting Board of Pharmacy action before considering the protocol.

The draft protocol has the therapy as two doses administered 12 hours apart within 72 hours of engaging in unprotected sex. However, recent studies indicate that emergency contraception drug therapy remains substantially effective up to 120 hours (5 days) after unprotected sex and one emergency contraceptive product (Plan B) can be administered in a single dose. While the efficacy of emergency contraception declines over time, it remains approximately 80% effective when taken within 120 hours (5 days). The newer timing and dosing regimens would expand access to emergency contraception and the single dosing of Plan B would greatly aid in patient compliance with the therapy. The studies support no increased risk or side effects to the longer

time period or the altered dosing regimen. The American College of Obstetricians and Gynecologists has not reviewed the revised timing and dosing issues.

RECOMMENDATION 2

That the Board of Pharmacy approve the proposed statutory changes regarding the intern program.

Discussion

The Licensing Committee has been reviewing the intern program during its last two meetings. Based on the committee's review and discussions, staff drafted modifications to the program. First and foremost, the modifications were drafted as a statute. This is because currently all intern requirements are in regulation and should be in statute. The changes include the following: a ratio of two interns to one pharmacist (this is consistent with current board policy), the requirement that the pharmaceutical experience comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education, and the elimination of the extension provision for the intern permit and the definition of a preceptor.

(Attachment B)

During the committee meeting, there were some recommended changes from the public to the proposal. The committee agreed with the recommended changes and directed staff to modify the language accordingly. The proposal was modified and shared with the interested parties for comment. Staff did receive feedback and some additional language changes. Some of the changes were added and are reflected in the proposed language found in attachment B. A copy of what was provided by the interested parties is also included for the board's consideration.

(Attachment C)

ACTION ITEM 3 (Not a Committee Recommendation)

That the Board of Pharmacy consider the approval of the School of Pharmacy at Lake Erie College of Osteopathic Medicine.

Discussion

The board received an intern pharmacist application from a student at Lake Erie College of Osteopathic Medicine, School of Pharmacy. This is a new school, which provides an accelerated PharmD program, which can be completed in three years. The first students admitted into this program are currently in their second year of instruction.

According to the Accreditation Council for Pharmacy Education (which until several months ago was known as the American Council on Pharmaceutical Education) or ACPE, this program has been ranked by that agency as "Precandidate Status."

Precandidate status is the lowest of the ACPE provisional accreditations, and students who graduate from such a school would not be eligible for pharmacist licensure. The ACPE states that

precandidate schools have the concepts of an acceptable ACPE program committed to paper, but the program components have not yet been fully implemented.

“Candidate Status” is the next provisional level of ACPE accreditation, which would allow graduates from such a school to become licensed pharmacists. In order to be fully ACPE accredited, the school must have graduated one class of students, among other conditions.

Internship is an integral part of the pharmacy education of students. This obviously creates a problem for students in such new programs where state licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework as a condition of issuing an intern license.

California Code of Regulations sections 1719, 1727 and 1729 require that intern licenses may be issued only to those students who attend ACPE or board-approved schools of pharmacy, and admission to the pharmacist licensure examination to graduates from ACPE or board-approved schools. The ACPE has not approved the Lake Erie College of Osteopathic Medicine, School of Pharmacy.

According to the ACPE, the ACPE extended the initial precandidate status for the school of pharmacy for six months because the school was not ready to move to the second provisional level of candidate status. However, a new ACPE review has been completed, and the ACPE board will take action on this review at its January 15, 2004 meeting.

During our board meeting, staff will provide an update on the actions of the ACPE board taken at its January meeting. The board needs to determine whether it wishes to recognize the School of Pharmacy at Lake Erie College of Osteopathic Medicine for purposes of issuing intern licenses, accepting intern hours and accepting the degree granted by the school of pharmacy. If it does not, the board will not issue intern licenses to this school’s students nor admit them to the board’s examination until ACPE accredits the school, which can occur no earlier than the first graduation of the school’s students.

For the next Licensing Committee meeting, staff will develop a process whereby the board can recognize new schools of pharmacy prior to being ACPE accredited.

NO ACTION

Workgroup with the Department of Health Services – State Food and Drug Branch on Pharmacy Compounding

Last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they

communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

It was agreed to establish this workgroup upon the conclusion of the committee's review of Pharmaceutical Benefit Managers (PBMs) and was added as a committee strategic objective. The Licensing Committee has begun the formation of the workgroup and has requested that Board Members John Tilley and Ken Schell participate along with Supervising Inspector Dennis Ming. The meeting will be public with all interested parties invited to attend.

Final Report on the Study on the Evaluation of Pharmacy Technicians in a Unit-Dose Drug Distribution System

Peter J. Ambrose, Pharm.D., Associate Clinical Professor for UCSF, School of Pharmacy will present the final report on the study on the evaluation of pharmacy technicians in a unit-dose drug distribution system. In May 1998, the Board of Pharmacy approved a study on the evaluation of pharmacy technicians in a unit-dose distribution system. The UCSF School of Pharmacy sponsored the study in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study ended on December 31, 2003. **(Attachment D)**

The Board of Pharmacy originally granted that waiver for the study pursuant to CCR section 1731 and the study was approved until November 1, 2000. Because of the delay in starting the study, the board extended the waiver until February 2001, and requested that UCSF, LBMMC and CSMC present the final report at its January 2001 meeting. When the final report was presented, the board agreed to extend the study another two years so that the study could be made permanent either through regulation or legislation. **(Attachment E)**

Implementation of NAPLEX and California Specific Examination

Staff has been working diligently to assure that the new examination structure is in place as soon as possible. The contracts for the NAPLEX and the California Pharmacist Jurisprudence Examination are in the final stages of completion. The goal is to be able to issue licenses to pharmacists who have taken (and passed) the new examinations by the end of March 2004. This would be the same time as when the board would have been able to license pharmacists had they taken the board's prior exam.

The intent is for applicants who will take the NAPLEX after January 1, 2004, to have that score be available to California. Applicants must designate California as a score transfer state before they actually take the examination.

The board will be able to administer the California Pharmacist Jurisprudence Examination via computer terminals in March 2004. The board will use the examination vendor under contract with the Department of Consumer Affairs for this portion of the examination instead of the NABP. The Competency Committee has developed a sufficient item bank of test questions for the new content outline for the examination, a significant task that required monthly meetings

since August. The examination items are ready. Information about the examination is on the board's Web site and it is updated periodically. (**Attachment F**)

Update on the Changes to the Pharmacy Technician Program

Beginning this month, the new changes to the licensure requirements for applicants seeking registration as pharmacy technicians took effect. These changes were the result of SB 361 (Figueroa, Chapter 361, Statutes of 2003).

Specifically, changes in Business & Professions Code section 4202 (a) alter the qualifying methods an applicant must satisfy to become registered. To be issued a technician registration, an applicant must satisfy one of the following criteria:

- Obtain an associate's degree in pharmacy technology;
- Complete a course of training specified by the board (this is 240 hours of theoretical and practical training provided by a technician training school or by an employer);
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

Meeting Summary of December 3, 2003 (Attachment G)

The meeting dates for 2004 are: March 3rd, June 9th, September 22nd, and December 1st. The members requested that the meetings start at 9:30 a.m. and be held either in Oakland or Burbank.

Status Report on Committee Goals for 2003/04 (Attachment H)

Attachment A



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THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

DISTRICT IX

WOMEN'S HEALTH CARE PHYSICIANS

January 13, 2004

John Jones, R.Ph.
President, California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814

VIA FACSIMILE 916/327-6308

RE: Draft Statewide Protocol for Pharmacists to Furnish Emergency Contraception (December 12, 2003); Licensing Committee Agenda Item at January 21, 2004 Board of Pharmacy Meeting

Dear President Jones:

On behalf of the American College of Obstetricians and Gynecologists, District IX, representing more than 4300 California physicians, we urge adoption of the proposed standardized protocol for pharmacists to furnish emergency contraception (EC), with minimal amendment. ACOG, District IX worked with the author and sponsors of the underlying legislation, Senate Bill 490 (Alpert, 2003) to craft a bill with which ACOG believes meets the tests of safety for those women seeking EC without physician consultation, and does not create a barrier to those women accessing EC. Under the legislation, the standardized protocol is to be completed by the Board of Pharmacy, in consultation with ACOG, District IX. We worked with the sponsors (the Public Health Institute) of the bill to design a draft protocol, and for the most part were able to agree on the document. We are in agreement with the proposed protocol, save for one important area and one housekeeping area.

Essential in the legislation was that these drugs, when used as EC are so safe, that minimal intervention needs to occur so that women can access EC as soon as possible after unprotected sexual intercourse. As EC is not over-the-counter, but is so safe that it does not necessarily need a physician consultation, pharmacists should be able to provide EC directly. However, as EC still is a prescription medication and not available without a prescription a protocol agreement is needed as a prescription substitute. ACOG's policy all through the legislation is that only two questions need to be asked by the pharmacist to establish the appropriateness of this medication. They are:

- 1) Whether the woman allergic to any drug and
- 2) has she had unprotected sexual intercourse within 72 hours.

Period. That's it. As testified to in multiple legislative committees, we believe further unnecessary personal questions create barriers to women accessing EC.

DISTRICT IX OFFICERS 2002-2005

CHAIR	VICE CHAIR	IMMEDIATE PAST CHAIR	SECRETARY	TREASURER
James A. Macer, MD 1000 Congress Street, #400 Pasadena, CA 91105	Frank R. Gamberdella, MD 504 W. Pueblo Street #201 Santa Barbara, CA 93105	Josephine Von Herzen, MD 550 Washington Street, #725 San Diego, CA 92103	Betty Tu, MD, MBA 17922 Fitch Irvine, CA 92614	Jeanne Conry, MD, PhD 8204 Cantershire Way Granite Bay, CA 95746

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We object to asking a woman for the date of her last menstrual period in order to rule out pregnancy as part of the standardized protocol. At first glance, asking for the LMP to rule out pregnancy appears helpful. However, it is unnecessary and can be problematic. First, a certain LMP date is not necessarily indicative of a pregnancy. A woman may have a varied menstrual cycle from normal, including polycystic ovarian syndrome which may leave a woman with amenorrhea for months. This does not mean she cannot conceive if her LMP was months ago and that she should not use EC after unprotected sexual intercourse.

What will occur if a woman cannot recall her last LMP or the LMP is longer ago than 2 weeks? Will she be refused the medication or made to take a pregnancy test? Either scenario is unacceptable. One of the beauties of EC is that it does not disrupt or otherwise interfere with an established pregnancy. It does not cause birth defects in the developing embryo. This being the case, asking the question of LMP to rule out pregnancy is unnecessary and we ask that the question be removed from the protocol.

One housekeeping issue – the EC Fact Sheet, which is distributed to patients, states that EC is most effective if taken within three days (72 hours) of unprotected sex. The protocol states that pharmacists should counsel clients that “EC effectiveness declines gradually over 5 days” (120 hours). Recent studies show that within 5 days may still be effective. ACOG’s clinical committees have not yet taken a position whether the proposed change from 3 days to 5 days should be supported. However, for the sake of clarity and consistency, we ask that the protocol reflect the 3 days until all concerned agree on changing the timing to 5 days, at which time the Fact Sheet should also be changed.

This protocol, with the deletion of “Date of last menstrual period to help rule out pregnancy” and the fix on the 3/5 day issue, is a document ACOG is proud to have worked on in consultation with the sponsors of SB 490, the Public Health Institute/Pharmacy Access Partnership. Approval and implementation of this protocol will allow full access of emergency contraception for women across the State of California thereby reducing the numbers of unplanned pregnancies – a goal we all share.

I plan to be in attendance at the Board meeting on January 21st if you would like to discuss this matter. If you have any comments or questions in advance of the meeting, please call me at 916/457-5217.

Sincerely,



Shannon Smith-Crowley, J.D., M.H.A.
Legislative Advocate

Cc: Paul Riches, Chief of Legislation and Regulation, CA Board of Pharmacy

Board of Pharmacy
Draft Protocol for Furnishing Emergency Contraception
January 21, 2004

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will assess the need for emergency contraception by determining:

- If patient is requesting EC for emergency use or advance need.
- Date of last menstrual period to help rule out pregnancy.
- If patient is allergic to any medications.

For emergency use:

- If patient had unprotected intercourse within the time limits established for effective use of emergency contraception.

When the pharmacist determines that furnishing emergency contraception is appropriate, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Timing: EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. The pharmacists should counsel clients that :

- EC effectiveness declines gradually over 5 days
- EC use will not interfere with an established pregnancy

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1 -- Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Brands and Doses Of Oral Contraceptive Tablets Used For Emergency Contraception

<i>Dedicated Emergency Contraception</i>				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

Appendix 2 -- Sample list of Anti-Emetics for Use with Emergency Contraception.

**Anti-nausea Treatment Options
for use with Emergency Contraception**

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</i>		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Appendix 3 – Title 16, Section 1707.1 of the California Code of Regulations

§1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
3. The date on which a drug was dispensed or refilled;
4. The prescription number for each prescription; and
5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, of the Business and Professions Code.

Reference: Sections 4005, 4121 and 4122, of the Business and Professions Code.

Attachment B

Board of Pharmacy
Proposed Changes to Intern Statutes
January 7, 2004

Amend Section 4005 of the Business and Professions Code, to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; and pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.¹

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.

(d) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Add Section 4026.5 to the Business and Professions Code, to read:

4026.5. "Good standing" means a license issued by the board that is unrestricted by disciplinary action taken pursuant Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.²

Amend Section 4030 of the Business and Professions Code, to read:³

4030. ~~"Intern pharmacist" means a person registered with the board pursuant to Section 4200 who shall have completed the educational requirements as determined by the board.~~ Intern pharmacist means a person issued a license pursuant to Section 4208.

¹ This authority was established in Section 4200 (a) (5) and is being moved to consolidate rule-making authority into one section.

² This is a commonly used term that needs to be better defined for clarity.

³ Modify the definition to ensure consistency throughout the law and updating the reference section.

Amend Section 4114 of the Business and Professions Code, to read:

4114. ~~An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the supervision of a pharmacist. The pharmacist shall not supervise more than one intern pharmacist at any one time.~~

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.⁴

(b) A pharmacist shall not supervise more than two intern pharmacists at any one time.⁵

Amend Section 4200 of the Business and Professions Code, to read:

4200. a) The board ~~shall~~ may license as a pharmacist, ~~and issue a certificate to,~~ any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has ~~received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates~~ been certified by the Foreign Pharmacy Graduate Examination Committee⁶.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has ~~had~~ earned 1,500 hours of ~~pharmaceutical~~ pharmacy practice experience ~~or the equivalent, in accordance with regulations adopted by the board~~ the Section 4209.⁷

~~(A) "Pharmaceutical experience," constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly related to the selling of drugs, compounding physician's prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.~~

~~(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.~~⁸

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

⁴ This moves the functions an intern may perform and under what conditions from regulation to statute.

⁵ The ratio requirement is becoming a separate subsection and being increased to two consistent with board policy.

⁶ Consistent with national standards, the board is requiring full certification. This certification will streamline the board's processing of board required documents.

⁷ Intern experience is now defined in Section 4209.

⁸ Moved to Section 4209 and specified compliance with the Accreditation Council for Pharmacy Education.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Add Section 4208 to the Business and Professions Code, to read:⁹

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in Section 4200 subdivision (a), paragraphs (1) – (4).

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be cancelled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student re-enrolls in a school of pharmacy recognized by the board to fulfill the education requirements of Section 4200 subdivision (a), paragraph (1) – (4).

Add Section 4209 to the Business and Professions Code, to read:¹⁰

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before applying for the pharmacist licensure examination.

(1) This pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist is required to submit proof of his or her experience on board-approved affidavits, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

⁹ This section moves from regulation to statute the definition of an intern as well as details the licensing requirements.

¹⁰ This section moves the experience requirements an intern must satisfy prior to licensure as a pharmacist from regulation to statute and consolidates information formerly included in Section 4200. This section requires that intern experience must be completed prior to applying and would eliminate a rarely used option for foreign educated applicants to petition the board for 600 hours of intern credit for experienced earned in another country.

ACPE - Standards of Curriculum

Proposed B+P Code section 4209(a)(1)

Standard No. 8. The Curriculum in Pharmacy

The College or School of Pharmacy should offer a curriculum in pharmacy intended to prepare its graduates to become generalist practitioners of pharmacy. The goals and objectives of the curriculum in pharmacy should embrace the scope of contemporary practice responsibilities as well as emerging roles that ensure the rational use of drugs in the individualized care of patients as well as in patient populations. The organized program of study should provide students with a core of knowledge, skills, abilities, attitudes, and values that are necessary to the provision of pharmaceutical care and should provide opportunity for selection by students of courses and professional experiences in keeping with particular interests and goals. The need for life-long learning should be reflected as an integral theme of the curriculum.

Standard No. 9. Curricular Organization and Length

The curriculum in pharmacy should provide sufficient content for the achievement of the professional competencies necessary to the general practice of pharmacy and to satisfy educational requirements for licensure as a pharmacist, and should meet the requirements of the institution for the doctor of pharmacy degree. The College or School of Pharmacy's organized plan of study should focus upon the content, sequence, process, and outcomes of the curriculum. The curriculum for the professional program in pharmacy requires a minimum of four academic years or the equivalent in order to ensure achievement of the professional competencies necessary to become a generalist practitioner who renders pharmaceutical care.

Standard No. 10. Professional Competencies and Outcome Expectations

Professional competencies that should be achieved through the College or School of Pharmacy's curriculum in pharmacy are an ability to:

- a. evaluate drug orders or prescriptions, accurately and safely compound drugs in appropriate dosage forms, and package and dispense dosage forms;
- b. manage systems for storage, preparation, and dispensing of medicines, and supervise technical personnel who may be involved in such processes;
- c. manage and administer a pharmacy and pharmacy practice;
- d. apply computer skills and technological advancements to practice;
- e. communicate with health care professionals and patients regarding rational drug therapy, wellness, and health promotion;
- f. design, implement, monitor, evaluate, and modify or recommend modifications in drug therapy to insure effective, safe, and economical patient care;
- g. identify, assess, and solve medication-related problems, and provide a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;
- h. evaluate patients and order medications and/or laboratory tests in accordance with established standards of practice;
- i. evaluate patient problems and triage patients to other health professionals as appropriate;
- j. administer medications;
- k. monitor and counsel patients regarding the purposes, uses, and effects of their medications and related therapy;
- l. understand relevant diet, nutrition, and non-drug therapies;
- m. recommend, counsel, and monitor patient use of nonprescription drugs;
- n. provide emergency first care;

- o. retrieve, evaluate, and manage professional information and literature;
- p. use clinical data to optimize therapeutic drug regimens;
- q. collaborate with other health professionals; and
- r. evaluate and document interventions and pharmaceutical care outcomes.

Outcome expectations for student performance in the professional competencies stated above should be set forth and measured by the College or School. The process of measuring outcome expectations should include student self-assessments of performance in the stated professional competencies.

Standard No. 11. Areas and Content of Curricular Core

The areas and content of the curriculum in pharmacy should provide the student with a core of knowledge, skills, abilities, attitudes, and values which, in composite, relate to the professional competencies and outcome expectations set forth in Standard No. 10. Professional Competencies and Outcome Expectations. The areas and content of the curriculum in pharmacy should be in phase with one another and should be balanced in accord with the College or School of Pharmacy's mission, goals, and objectives. The areas and content of the curricular core are as follows:

biomedical sciences, including content in anatomy, physiology, pathophysiology, microbiology, immunology, biochemistry, molecular biology, and biostatistics;

pharmaceutical sciences, including content in medicinal chemistry, pharmacognosy, pharmacology, toxicology, and pharmaceutics which encompasses physical/chemical principles of dosage forms and drug delivery systems, biopharmaceutics, and pharmacokinetics;

behavioral, social, and administrative pharmacy sciences, including content in health care economics, pharmacoeconomics, practice management, communications applicable to pharmacy, the history of pharmacy, ethical foundations to practice, and social and behavioral applications and laws pertaining to practice;

pharmacy practice, including content in prescription processing, compounding and preparation of dosage forms, including parenteral products, drug distribution and drug administration, epidemiology, pediatrics, geriatrics, gerontology, nutrition, health promotion and disease prevention, physical assessment, emergency first-care, clinical laboratory medicine, clinical pharmacokinetics, patient evaluation and ordering medications, pharmacotherapeutics, disease-state management, outcomes documentation, self care/non-prescription drugs, and drug information and literature evaluation; and

professional experience, including introductory and advanced practice experiences acquired throughout the curriculum as a continuum, progressing from the Introductory Pharmacy Practice Experiences through the Advanced Pharmacy Practice Experiences in a variety of practice settings.

Guideline 11.1

Instruction in the use of new and innovative technologies in the provision of pharmaceutical care, such as information systems and biotechnology, should be integrated throughout the areas and content of the core curriculum.

Guideline 11.2

The biomedical and pharmaceutical sciences should be of such depth, scope, timeliness, quality, sequence, and emphasis to provide the foundation for and support of the intellectual and clinical objectives of the professional program in pharmacy. The biomedical sciences should provide the basis for understanding and treating humans in health and disease. Where instruction is provided in the biomedical sciences by other academic units of the University, these areas should be developed in accord with the goals and objectives for the curriculum in pharmacy. Appropriate liaison mechanisms should be established to insure effective instructional delivery and to assure satisfaction of biomedical science objectives for the professional program in pharmacy.

Guideline 11.3

The behavioral, social, and administrative pharmacy sciences should provide the basis for understanding and influencing human behavior in health and disease, in the management process of pharmacy, and in pharmacy's interrelationships with health care systems. The behavioral, social, and administrative pharmacy sciences should attend to the knowledge, skills, abilities, attitudes, and values necessary to the efficient and effective management of patient-centered practice, including administrative and management matters related to

drugs and supplies, as well as administrative and management activities related to personnel and finances. Moreover, the behavioral, social, and administrative pharmacy sciences area should contribute to the development and implementation of care plans and to the management of the patient's drug therapies.

Guideline 11.4

The professional experience should be of adequate intensity, breadth, and duration so as to support achievement of stated competencies as demonstrated by assessment of outcome expectations. Students should be duly enrolled in the College or School of Pharmacy and should not receive monetary remuneration for professional experience so as to assure the primacy of an appropriate student/teacher relationship.

Guideline 11.5

The Introductory Pharmacy Practice Experiences should be offered in various practice settings during the early sequencing of the curriculum for purposes of providing transitional experiential activities and active learning. Such practice experiences should be organized as a curricular progression leading to advanced practice experiences so as to support growth in the student's capabilities to render pharmaceutical care. The scope and breadth of the introductory experiences should involve the initial development of practice skills, and should be consistent with these stated purposes. A quality control procedure should be established in accord with stated purposes and outcome expectations; the Introductory Pharmacy Practice Experiences may be designed in conjunction with didactic courses or as a discrete experiential offering.

Guideline 11.6

The Advanced Pharmacy Practice Experiences should provide active participation and in-depth experiences to acquire practice skills and judgment and to develop, in a graded fashion, the level of confidence and responsibility needed for independent and collaborative practice. Toward this end, a spectrum of practice experiences should be deployed wherein the biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and pharmacy practice are integrated, professional knowledge and skills are applied, and professional attitudes, ethics, and behaviors are developed so as to enable students to provide pharmaceutical care. Advanced practice experiences should enhance communication and collaborative skills with patients and other professionals, including the ability to work and communicate effectively with diverse colleagues and patients. The advanced practice experiences should also provide experience in prescription processing, compounding and preparation of dosage forms, including parenteral products, drug distribution systems, documentation of services, the taking of drug histories, participating in drug therapy decisions, monitoring, educating, and counseling patients, solving problems, and systematically evaluating drug use. Advanced practice experiences should include application of clinical pharmacokinetic principles in the development and management of dosing and should incorporate knowledge and skills in the searching, analysis, and interpretation of drug information. Students should be under the close supervision of pharmacist role models.

Guideline 11.7

The organization of the Advanced Pharmacy Practice Experiences should provide a balanced series of core and selective experiences that cumulatively provide sustained experiences of adequate intensity, breadth, and duration to enable achievement of stated competencies as demonstrated by assessment of outcome expectations. Generally, the core and selective experiences should be full-time and provide continuity of care, with pharmacy faculty supervision and monitoring. The duration of the Advanced Pharmacy Practice Experiences should ordinarily be the equivalent of one academic year. Core experiences should develop pharmaceutical care capabilities in inpatient and ambulatory care settings, especially community pharmacies. Selective experiences should complement the core experiences and provide adequate and innovative opportunities for students to mature professionally in accord with their individualized interests. The series of core and selective experiences should be philosophically and educationally coordinated to achieve, in composite, the experiential whole of the Advanced Pharmacy Practice Experiences.

Guideline 11.8

The Advanced Pharmacy Practice Experiences should be provided in both ambulatory and inpatient settings and should include primary, acute, chronic, and preventive care among patients of all ages. The core experiences should provide substantial experience in community pharmacy practice and hospital/institutional pharmacy practice, as well as substantial practice experience with general medicine acute care patients. Most of the advanced practice experiences should involve direct patient care. However, some of the advanced practice experiences may involve indirect patient care or may occur in non-patient care areas, such as research and management. Other experiences, such as those in drug information, managed care, and home health care should be available.

Guideline 11.9

A quality control procedure for the Advanced Pharmacy Practice Experiences should be established for core and selective experiences so as to facilitate achievement of stated competencies, provide for feedback, assure reasonable standardization, and insure consistency in evaluation. The College or School should assure that all practice facilities utilized for the advanced practice experiences meet and sustain conditions necessary to the delivery of pharmaceutical care and to the students' learning needs through the establishment of a mechanism such as the use of a review council. This review council, or other established mechanism for quality control, should involve individuals with appropriate expertise and perspectives, such as student, practitioner, and board of pharmacy representation. The core and selective experiences should be organized, administered, and evaluated in accord with their individualized goals and objectives and in keeping with the overall goals and objectives for the advanced practice experiences. General objectives and learning modules as well as site specific guidelines should be established for the core and selective experiences. Specific criteria should be developed so as to enable faculty and students to assess both formative and summative progress. Students should be provided the opportunity to demonstrate achievement of stated competencies as evaluated through the use of reliable, validated criteria.

Attachment C



Steve.W.Gray@kp.org

12/16/2003 06:19 PM

To: Paul_Riches@dca.ca.gov

cc: jcronin@inreach.com, "Rho, Jay P" <Jay.P.Rho@kp.org>, teri.miller@cshp.org

Subject: Re: Intern Changes

Paul

Enclosed is a document with recommended changes from Kaiser Permanente. The additions are listed as double underlined ALL CAPS. The deletions are shown as "strike throughs". Sometimes formatting does not translate between different e-mail systems. However, since I put it in a WORD document, it should do fine.

Reason for Changes:

1. The first change (from "pharmaceutical experience" to "pharmacy practice experience" is more than just semantical. It reflects the much broader practice and responsibilities of modern practice rather than just dealing with "pharmaceutical products". The reasoning is similar to why APhA changed its name after 150 years from "Pharmaceutical Associations" to "Pharmacist Association. (Note: We asked them to change it to "Pharmacy Association" because the membership includes more than just pharmacists.)

2. The second change, i.e. in new section 4029 (a)(1), is to provide the Board with statutory authority to adopt regulations that may differ from ACPE curriculum requirements without having to go back to the Legislature. The "or" would allow the Board to do nothing until it is needed. ACPE is NOT always on the leading edge. For example, I believe ACPE is severely lacking in compounding curriculum. ACPE seems to be overly influenced by Eastern schools.

3. The third change is very, very serious. We discussed it at the Licensing Committee meeting. Under the proposed language, if taken literally, the only way an intern could rely upon being able to get all of his/her experience certified is to carry a packet of affidavits with him/her and ask each pharmacist that supervised him/her to sign one before the pharmacist leaves his/her presence. Otherwise, if that pharmacist is not around when the intern needs the certification, nobody else can sign the document even if he knew personally of the experience or had review departmental records of the training accomplishments.

Our recommended changes make it more clear that as with all other affidavits the pharmacist is signing in good faith upon and concept known as "information and belief". However, I believe best not to use legal jargon. The signing pharmacist may not have been present during the performance of the tasks by the intern or may not have even been licensed. However, if the pharmacist acts upon good faith and reliable records and information and from a pharmacist who is under the jurisdiction of the Board at the time the information was provide, that should be sufficient to substantiate the experience.

I have sent a copy to John Cronin for consideration on behalf of CPhA and to Terri Miller and Jay Rho. I believe this is a very important issue for California pharmacists, especially in light of the Board's recent admonishments and discipline of pharmacists for signing affidavits regarding experience that they did not personally witness.

For example the Board has invalidated certifications where, for instance, a 4th year intern worked side-by-side with a third-year intern and then became a pharmacist and was asked by the lower classmate to sign the affidavit. The Board said in its recent newsletter that even if this pharmacist was the pharmacy manager and had personal knowledge of the experience he could not sign the affidavit because he was not the supervising pharmacist or even a licensed pharmacist at the time of the intern's experience. That is ridiculous. The pharmacist, as manager or otherwise, should be able to sign an affidavit if he/she believes in good faith that the intern actually had the experience. It should be sufficient that if challenged that pharmacist should be able to reasonably explain or provide evidence upon which he or she relied to form the belief, such as the hospital pharmacy's training records, etc.

Likewise the employer should be able to designate which pharmacist "in good standing" can sign certifications based on company training policies and records. It should not have to be a pharmacist who directly supervised the intern or even a pharmacist who supervised the supervising pharmacist. If this concept is not adopted, as mentioned, the only way an intern could protect himself/herself from not having the right pharmacist around when the certification is needed is to have the supervising pharmacist sign an affidavit after every change in supervising pharmacist, which might means several times per shift. For example, we have staffed shifts for pharmacists. An

intern coming to work after school hours may have part of his or her shift "supervised" by several different pharmacists who each leave work before the intern's shift is over.

Paul Riches

@dca.ca.gov

To: jcronin@inreach.com, Steve W Gray/CA/KAIPERM@KAIPERM

cc:

Subject: Intern Changes

12/16/2003

02:49 PM

Greetings,

Attached is a revision of the changes to the intern program per comments we received at the December 2003 Licensing Committee. Let me know if you have any comments.

Thanks.

Paul Riches, Chief of Legislation and Regulation
CA Board of Pharmacy
(916) 445-5014 ext. 4016

(See attached file: Intern Changes For Jan 04 Brd Mtg.doc)

----- Attachment(s) have been removed -----



- Rec Changes to BOP Intern Changes For Jan 04 Brd Mtg.doc

**Board of Pharmacy
Proposed Changes to Intern Statutes
December 16, 2003**

Amend Section 4005 of the Business and Professions Code, to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; ~~and~~ pertaining to the sale of drugs by or through any mechanical device; and relating to pharmaceutical experience necessary for licensure as a pharmacist.¹

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.

(d) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Add Section 4026.5 to the Business and Professions Code, to read:

4026.5. "Good standing" means a license issued by the board that is unrestricted by disciplinary action taken pursuant Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.²

Amend Section 4030 of the Business and Professions Code, to read:³

4030. ~~"Intern pharmacist" means a person registered with the board pursuant to Section 4200 who shall have completed the educational requirements as determined by the board.~~ Intern pharmacist means a person issued a license pursuant to Section 4208.

¹ This authority was established in Section 4200 (a) (5) and is being moved to consolidate rule-making authority into one section.

² This is a commonly used term that needs to be better defined for clarity.

³ Modify the definition to ensure consistency throughout the law and updating the reference section.

Amend Section 4114 of the Business and Professions Code, to read:

~~4114. An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the supervision of a pharmacist. The pharmacist shall not supervise more than one intern pharmacist at any one time.~~

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.⁴

(b) A pharmacist shall not supervise more than two intern pharmacists at any one time.⁵

Amend Section 4200 of the Business and Professions Code, to read:

4200. a) The board ~~shall~~ may license as a pharmacist, ~~and issue a certificate to,~~ any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates been certified by the Foreign Pharmacy Graduate Examination Committee⁶.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has ~~had~~ earned 1,500 hours of pharmaceutical experience or the equivalent, in accordance with ~~regulations adopted by the board the~~ Section 4209.⁷

~~(A) "Pharmaceutical experience," constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly related to the selling of drugs, compounding physician's prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.~~

~~(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.~~⁸

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

⁴ This moves the functions an intern may perform and under what conditions from regulation to statute.

⁵ The ratio requirement is becoming a separate subsection and being increased to two consistent with board policy.

⁶ Consistent with national standards, the board is requiring full certification. This certification will streamline the board's processing of board required documents.

⁷ Intern experience is now defined in Section 4209.

⁸ Moved to Section 4209 and specified compliance with the Accreditation Council for Pharmacy Education.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Add Section 4208 to the Business and Professions Code, to read:⁹

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in Section 4200 subdivision (a), paragraphs (1) – (4).

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be cancelled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student re-enrolls in a school of pharmacy recognized by the board to fulfill the education requirements of Section 4200 subdivision (a), paragraph (1) – (4).

Add Section 4209 to the Business and Professions Code, to read:¹⁰

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before applying for the pharmacist licensure examination.

(1) This pharmaceutical experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education.

(b) An intern pharmacist is required to submit proof of his or her experience on board-approved affidavits, which shall be certified by a pharmacist under whose supervision such experience was obtained.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

⁹ This section moves from regulation to statute the definition of an intern as well as details the licensing requirements.

¹⁰ This section moves the experience requirements an intern must satisfy prior to licensure as a pharmacist from regulation to statute and consolidates information formerly included in Section 4200. This section requires that intern experience must be completed prior to applying and would eliminate a rarely used option for foreign educated applicants to petition the board for 600 hours of intern credit for experienced earned in another country.

Attachment D



University of California
San Francisco

RECEIVED BY CALIF.
BOARD OF PHARMACY
2004 JAN -8 PM 2:41

LA/OC Area Clerkship Program
Department of
Pharmacy Services
Long Beach Memorial
Medical Center
2801 Atlantic Avenue
P.O. Box 1428
Long Beach, CA 90801-1428
tel: 562/933-0289
fax: 562/933-2348

January 7, 2004

Patricia F. Harris
Executive Director
California State Board of Pharmacy
400 "R" Street, Suite 4070
Sacramento, CA 95814-6200

Re: Conclusion of Technician Study

Dear Ms. Harris:

This report concludes the experimental program to evaluate pharmacy technicians in a unit-dose drug distribution system; sponsored by the UCSF School of Pharmacy, in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study began in June 1998, continued through December 2003, and has now ended.

Additions and deletions of certified pharmacy technicians since my last report are listed on the attached documents. The quality assurance audits were conducted at both institutions, and the audit data is also attached.

We have previously submitted to you a copy of the results of the experimental program that were published in the American Journal of Health-System Pharmacy in June 2002. The audits conducted since that publication serve as additional data that supports the conclusions in the manuscript.

The results from this study are consistent with those observed in other published studies in several other states. My conclusion is that trained pharmacy technicians can safely and accurately perform the routine and non-discretionary drug distribution tasks of checking unit dose medication cassettes, after the medication order has been evaluated and approved by a pharmacist. The advantage of this is that pharmacists can be utilized to provide professional services that will ensure the most appropriate, most efficacious and safe use of medications rather than spending their time stocking medication cassettes. To demonstrate this, I am including graphical data from CSMC that depicts the increase in drug therapies that were managed by pharmacists and potential adverse drug events prevented by pharmacists during the study period. At LBMMC, long-term, significant involvement in management of drug therapies and prevention of potential adverse drug events has also existed. The study supported a high degree of involvement in these activities despite an increasing

patient census and distribution workload. For 2003, the number of patient-days of pharmacist-managed drug therapy (requested by physicians) was 120,910.

Again, I sincerely appreciate the Board's support and approval to conduct the study. I trust that the Board will find the data we obtained useful in making objective decisions in the interest of patient care. As you requested, I will be prepared to give a brief presentation to the Board on the afternoon of January 21. I have also asked representatives from CSMC and LBMMC to participate with me.

Respectfully submitted,



Peter J. Ambrose, Pharm.D.
Professor of Clinical Pharmacy
School of Pharmacy
University of California, San Francisco

Enclosures:

- Eligible Technician Checkers – Cedars Sinai Medical Center
- Audits – Cedars Sinai Medical Center
- Audits – Long Beach Memorial Medical Center
- Graph – Drug Therapy Management by Pharmacists at CSMC
- Chart – Potential Adverse Drug Events Prevented at CSMC
- Graph – Potential Adverse Drug Events Prevented at CSMC

c: Frank Saya, Pharm.D.
Dale Adams, Pharm.D.
Rita Shane, Pharm.D.



CEDARS-SINAI MEDICAL CENTER.

DEPARTMENT OF PHARMACY SERVICES

8700 BEVERLY BLVD. A-845

LOS ANGELES, CA 90048

REPORT TO CALIFORNIA STATE BOARD OF PHARMACY (DECEMBER 2003)

TECHNICIAN CHECKERS NO LONGER ELIGIBLE:

Name of Technician	Board Registration No.	Reason
Edna Sotelo	TCH 19162	Promotion to other job function which does not require cart checking

TECHNICIAN CHECKERS RE-ELIGIBLE:

Name of Technician	Board Registration No.	Reason
Jose Camacho	TCH 13886	Re-certified upon return to the department from a medical leave

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Reg. #	Name Submitted In	MONTHLY / QUARTERLY AUDITS												MONTHLY / QUARTERLY AUDITS																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
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ed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Oct-00	Nov-00	Dec-00	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02	Feb-02	Mar-02	Apr-02	May-02	Jun-02	Jul-02
1			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
2			Passed			Passed			Passed			Passed			Passed			Passed	Newly Certified	Passed	Passed	Passed	Passed	Passed
3			Passed			Passed			Passed			Passed			Passed			Passed	Newly Certified	Passed	Passed	Passed	Passed	Passed
4																			Newly Certified	Passed	Passed	Passed	Passed	Passed
5																								Passed
6			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
7			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
8			Passed			Passed			Passed			Passed			Passed			Passed	Newly Certified	Passed	Passed	Passed	Passed	Passed
9																								Passed
10			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
11			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
12			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
13			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
14																			Newly Certified	Passed	Passed	Passed	Passed	Passed
15			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
16			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
17																								
18																								
19			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
20			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
21			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
22			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
23																								
24																								
25			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
26			Passed			Passed			Passed			Passed			Passed			Passed			Passed			Passed
		AVERAGE	99.92%				99.94%		99.97%		99.99%				100%			99.95%			99.95%			99.91%

Monthly/Quarterly Audits for CSMC

No.	Last Name	First Name	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	Jun-03	Jul-03	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03
1																			
2																			
3			Passed		Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
4			Passed		Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
5																			
6																			
7																			
8																			
9			Passed		Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
10																			
11																			
12																			
13																			
14																			
15			Passed		Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
16																			
17																			
18																			
19																			
20																			
21																			
22																			
23																			
24																			
25																			
26																			
AVERAGE					Passed	99.88%		Passed	99.97%		Passed	99.88%		Passed	99.98%		Passed	99.97%	

Long Beach Memorial Medical Center
December 2003

				CERTIFICATION		MONTHLY AUDITS				
No.	Last Name	First Name	Reg. #	Name Submitted in	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99
1					I	I	I	C	I	C
3					C	C	I	I	I	I
11									C	A
12									C	A
13										C
16										
17										
18										
19										
20										
21										
22										
23										
				Ave. Accuracy Rate	99.9%	99.9%	99.8%	99.8%	99.9%	99.9%

C =Certifying
A =passed Audit
F =Failed audit
I =Inactive
rC = Recertification

Long Beach Memorial Medical Center
December 2003

Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00
A	A	A	I	I	I	I	I	I	I	rc(379)	I	I	I	rc(1174)
A	A	A	I	I	I	I	I	I	I	I	rc(635)	I	I	rc(258)
A	A	A	A		A		A				A			
A	A	A	A	A			A				A			
A	A	A	A	A			I	I	I		A			
			C	A	I	I	I	I	C	I	I	I	I	rc(865)
										C	A	I		rc(612)
99.9%	99.9%	99.9%	99.9%	99.9%	100.0%		99.9%		99.9%	99.8%	99.9%		99.8%	99.8%

Long Beach Memorial Medical Center
December 2003

Quarterly Audits

Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02	Feb-02	Mar-02
rc(982)	I	I	I	I	I	rc(1102)	A(550)	A(511)	A(625)			A(522)		A(555)
I	I	I	rc(1078)		rc(2043)	I								
I	I	rc(992)	rc(513)	I	I	rc(1824)	A(586)	A(589)	A(727)			A(1029)		A(572)
I	I	I	I	I	I	rc(1008)	rc(1388)			rc(1150)	A(1027)			rc(1243)
						C(3617)	A(1080)	A(585)	A(1458)				rc(1464)	
							C(3008)							
							C(2822)							
99.8%	99.8%	99.8%	99.8%		99.9%	99.9%	99.9%	99.9%	99.9%	100.0%	100.0%	99.9%	99.9%	99.9%

Long Beach Memorial Medical Center
December 2003

[illegible]

Study Discontinued in this area.

Monthly/Quarterly Audits
Long Beach Memorial Medical Center

MCH Tech check Tech Audits

	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	Jul-03	Oct-03
Technician							
	A(548)				A(644)	A(530)	A(510)
C(1620)	C(509)	C552)	C524)		A(594)	A(525)	A(587)
	A(545)				A(644)	A(501)	A(582)
	A(692)				A(592)	A(515)	A(587)
	A(586)				A(6008)	A9563)	A(534)
	A(606)				A(561)	A(983)	A(517)
	LOA				A(573)	A(518)	LOA

A=monthly audit

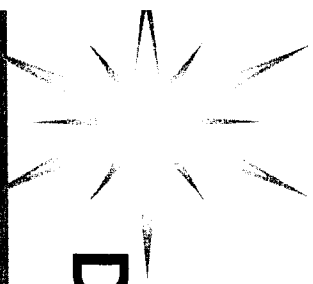
C=certification audit

I=inactive

LOA=medical leave

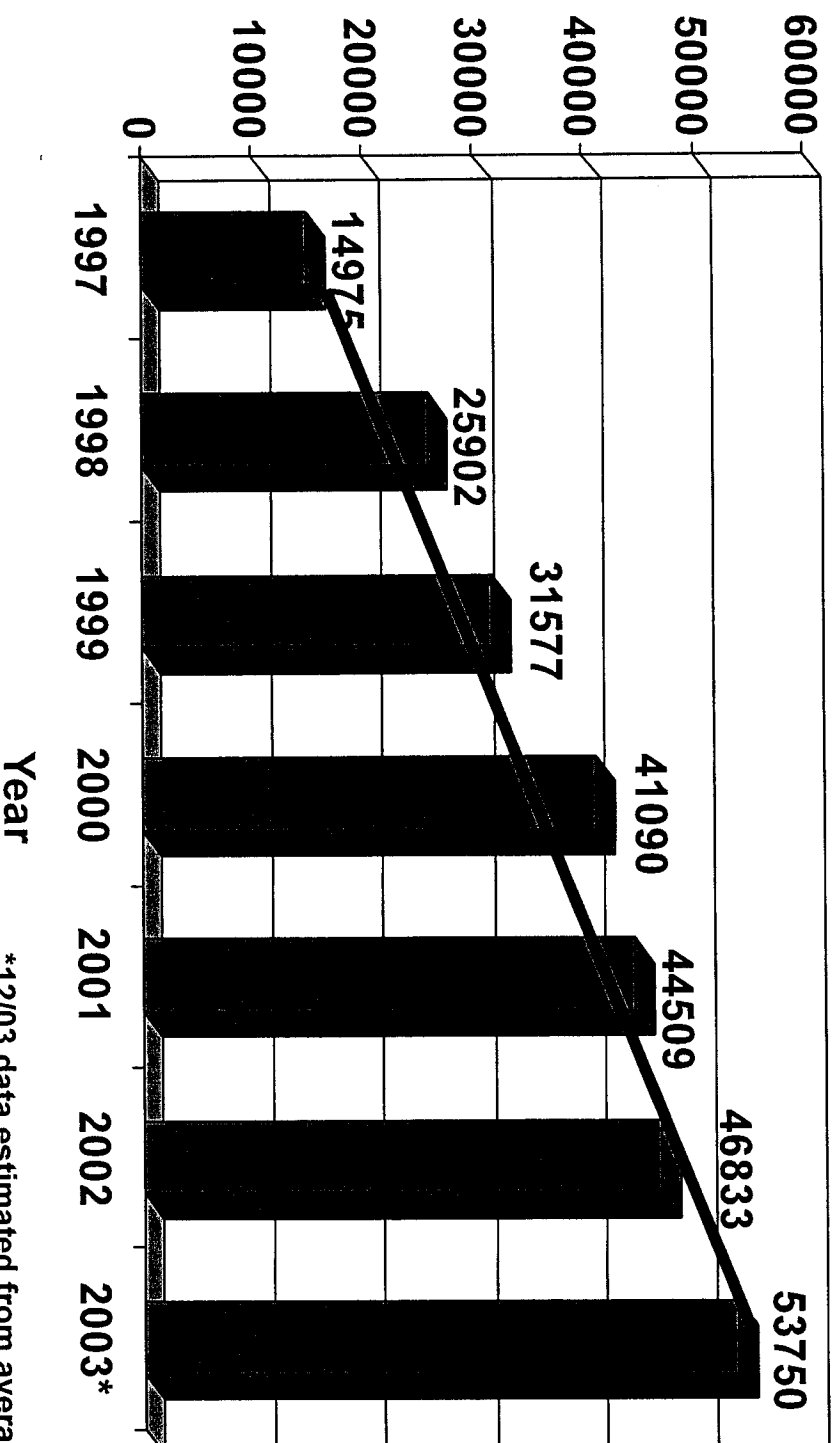


CEDARS-SINAI MEDICAL CENTER.



Drug Therapy Management by Pharmacists

Patient-Days of Rx-Managed Drug Therapy
(therapy requested by Physicians)



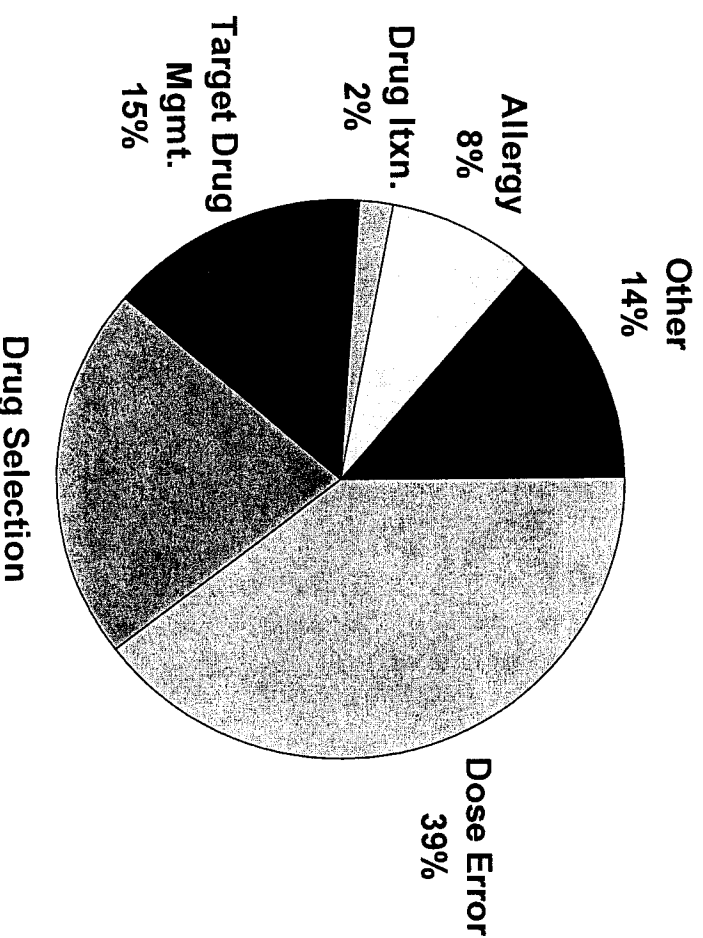
*12/03 data estimated from average of 1/03-11/03

Potential Adverse Drug Events Prevented September '02 - September '03

Daily Activities Include

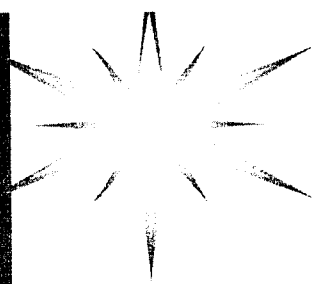
❖ **> 285 Routine Interventions/Day**
(14% increase from September '01-'02)

❖ **> 430 Clinical Inpatient Encounters/day**
Includes Code Blue attendance, MD drug info, PK/lab follow-up, clinical patient rounds, and protocol initiation/follow-up.
(15% increase from September '01-'02)

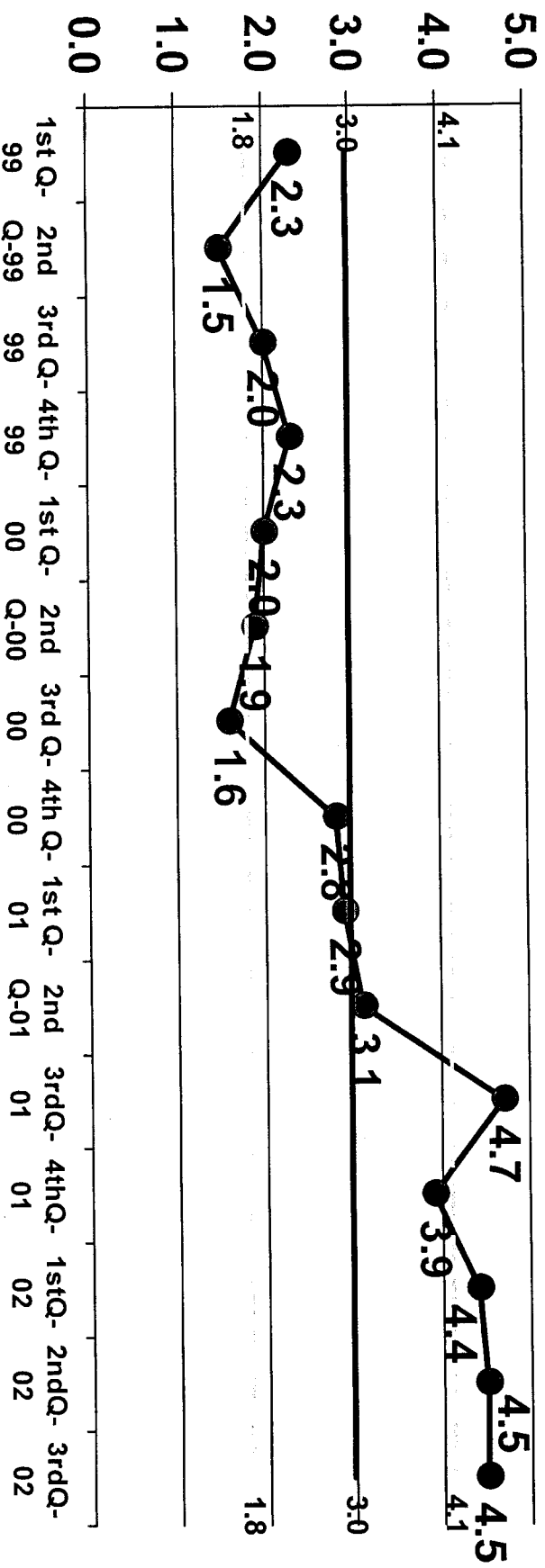
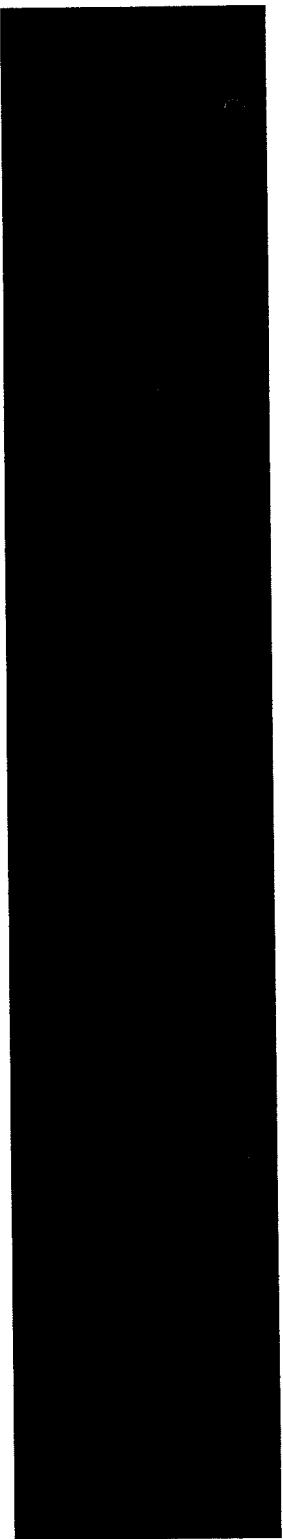


◆ **2041 Total Significant Interventions**
(consistent in comparison to Sept. '01-'02)

◆ **95% Acceptance Rate**
(consistent in comparison to Sept. '01-'02)



Potential Adverse Drug Events Prevented by Pharmacist Intervention



Attachment E



**CEDARS-SINAI MEDICAL CENTER
DEPARTMENT OF PHARMACY SERVICES**

The Department of Pharmacy Services at Cedars-Sinai Medical Center provides 24-hour clinical pharmacy services via satellite pharmacies. Additionally, the Ambulatory Care Pharmacy serves the Ambulatory Care Center clinics and prepares discharge, emergency room, and employee prescriptions. The Department consists of over 170 staff members. The Department provides state-of-the-art services of the highest quality that foster the efficacy, safety, and cost-effectiveness of medication use to ensure optimal outcomes by:

- Interpretation, evaluation, and clarification of medication orders to assure the absence of drug allergies and interactions and the optimal selection of dose, dosage form, route, and duration of therapy.
- Management of drug therapies such as anticoagulation, aminoglycosides and other medications in accordance with guidelines approved by the Pharmacy and Therapeutics Committee.
- Therapeutic management clinics for outpatients in areas such as anticoagulation, diabetic teaching, PPD, compliance
- Providing drug information to medical staff, housestaff, nurses, and hospital personnel.

Inpatient Programs and Services

Drug Information

Anticoagulation Management

Antimicrobial Utilization Evaluation

Medication Error and Adverse Event Evaluation

Investigational Drug Studies

Immune Disorders

Psychiatry

Transplantation

Oncology

Pediatrics

Medical and Surgical Critical Care

CPR Team Participation

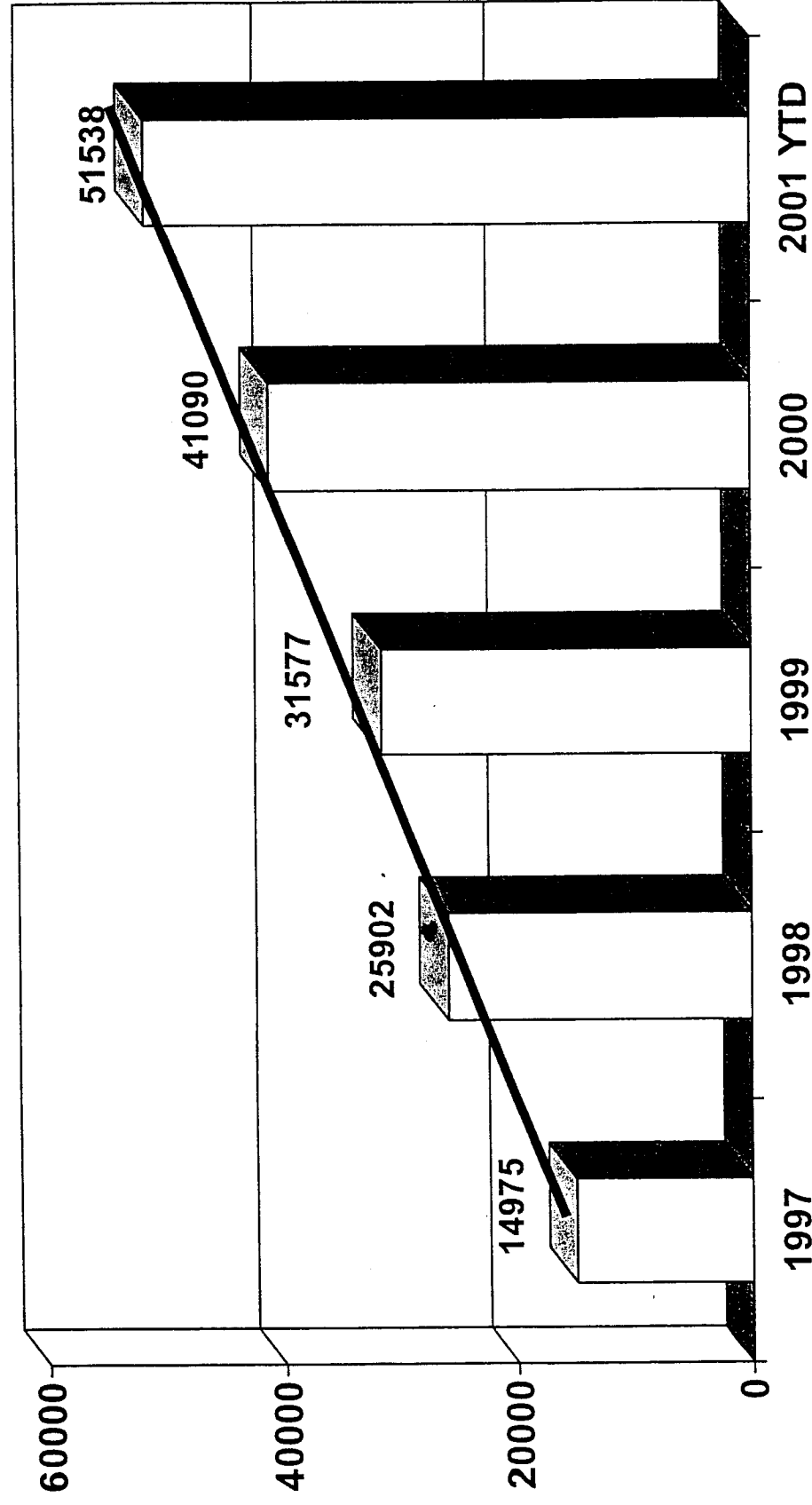
Pharmacokinetic Dosing

Anticoagulation Management

Rounds

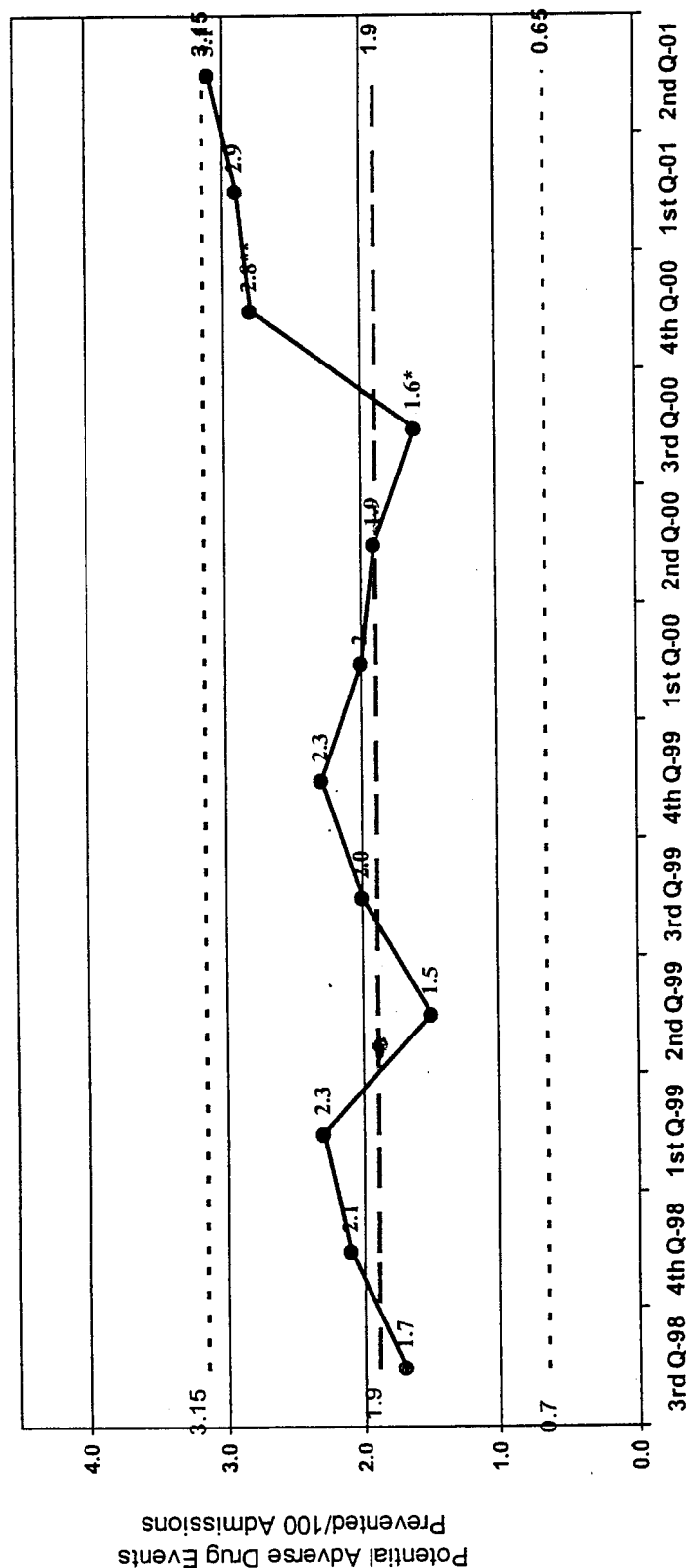
Medication Use Evaluation

Drug Therapy Management by Pharmacists: # Patient-Days of Rx-Managed Drug Therapy (requested by Physicians)



Potential Adverse Drug Events Prevented by Pharmacist Intervention

- Significant Adverse Drug Events Prevented/100 admissions
- - - - Upper/Lower Natural Process Limit
- — Average Value



* 3rd Q'00 downward trend due to new staff hiring & training.
 **4th Q'00 increase due to specific pediatric focus study.

11-Oct-01

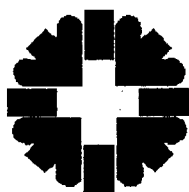
Report for an Experimental Program to Evaluate the Use of Board-Registered Pharmacy Technicians in Checking Medication Cassettes in a Unit-Dose Drug Distribution System

A Collaborative Study Between



UNIVERSITY OF CALIFORNIA, SAN
FRANCISCO
SCHOOL OF PHARMACY

*and the
Pharmacy Services Departments of*



LONG BEACH MEMORIAL
MEDICAL CENTER

and



CEDARS-SINAI MEDICAL CENTER.

January 24, 2001

Report from Peter J. Ambrose, Pharm.D., Associate Clinical Professor at the University of California, San Francisco, School of Pharmacy; in collaboration with Long Beach Memorial Medical Center and Cedars-Sinai Medical Center

Experimental Program to Evaluate the Use of Board-Registered Pharmacy Technicians in Checking Medication Cassettes in a Unit-Dose Distribution System

Presented to the
California Board of Pharmacy

January 24, 2001

Introduction & Purpose

Pursuant to our request at the Board of Pharmacy meeting on May 27, 1998, the Board granted a waiver of California Code of Regulations section 1793.7 to conduct an "experimental program" as authorized by CCR 1731. The waiver was granted to Long Beach Memorial Medical Center and Cedars-Sinai Medical Center, under the direction of the University of California, San Francisco, School of Pharmacy; for an experimental program: *Evaluating the Use of Board-Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System*. A copy of the initial proposal is attached. The purpose of the experimental program was to evaluate and compare the accuracy of checking unit-dose medication cassettes between licensed pharmacists and registered pharmacy technicians in the inpatient setting, after the cassettes had been filled (stocked) by other registered pharmacy technicians. The waiver was initially granted until November 1, 2000, and the Board extended the waiver until February 1, 2001 at their meeting in October 2000, at the request of CSMC and LBMMC.

Methodology

The unit-dose distribution system employed by both CSMC and LBMMC is depicted in the flow Diagram. It should be emphasized that the process of filling and checking unit-dose medication cassettes is preceded by having a licensed pharmacist review and approve all patients' medication orders. This review and verification process includes the pharmacist evaluating the appropriateness and accuracy of the medication, dosage form, route of administration and the dosage; and screening for drug allergies, drug-drug interactions and contraindications the individual patient may have. Again, this occurs before the filling and checking activities. Pharmacy technicians were utilized for manipulative and non-discretionary functions, and only under the supervision of a licensed pharmacist. To fill or stock a medication cassette with unit-dose medications, a technician simply reads a list of medications (a fill list) previously verified by a pharmacist, takes the unit-dosed medication off the shelf and places it in a patient's cassette or medication drawer. The next step consists of another person (a checker) checking the filled cassettes to minimize the possibility of errors before the medications

are issued to a nurse. It should be noted that nurses additionally check the medication when removing it from the patient's cassette, and confirm it with the medication administration record (which is a list of medication orders that were reviewed and approved by a licensed pharmacist) before administering the medication to the patient, in accordance with JCAHO and DHS requirements. Thus, there is in essence a triple-check process. Technicians do not evaluate the accuracy and appropriateness of a medication order. All professional judgment and decisions relating to pharmaceuticals are conducted by a licensed pharmacist.

As per the proposal approved by the Board, the study was conducted at both CSMC and LBMMC, and consisted of two parts:

- Part I: Assessment of pharmacist baseline checking accuracy, development of technician training program and certification of technicians.
- Part II: Certified technicians were responsible for checking unit-dose medication cassettes as part of their daily activities, after they completed the didactic and practical sessions

In Part I, a baseline of the accuracy rate for pharmacist checkers was obtained at both CSMC and LBMMC, according to the methodology presented to, and approved by, the Board. This included introducing random artificial errors into the unit-dose drawers of at least one error per 500 doses (this being equal to the target of 99.8% checking accuracy). In addition, the Pharmacy Services Departments at CSMC and LBMMC collaborated on a training syllabus, qualifying exam, data collection forms, and strategies for training technicians, and for data capture. Technicians were eligible to be entered into the study if they were Board-registered technicians or interns, and had at least six months of experience filling unit-dose medication cassettes. They were then given didactic and practical training, as outlined in the proposal methodology. The practical evaluation consisted of auditing the checking accuracy of the technicians for at least 3500 consecutive doses (may be divided into separate audits). To become a certified checker, a technician must have an overall accuracy rate of at least 99.8%. This phase of the study was begun in June 1998, and has been continued since then as new technicians were trained and added to the study. The Board was notified when technicians were added or dropped from the study in the bi-annual reports submitted.

Part II of the study was begun in April 1999. In this phase of the study, certified technicians who had successfully completed the didactic and practical sessions were responsible for checking unit-dose drawers as part of their daily activities. Monthly audits of at least 500 doses were conducted on these certified technicians using the same procedure of planting random artificial errors. Accuracy was to be maintained at 99.8% or higher. The methodology outlined that if a technician failed a monthly audit, then the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position, retrained and re-certified in checking. If a technician did not check unit-dose drawers for longer than three months,

an audit would be conducted when the technician re-started checking. If a technician had not checked cassettes for longer than six months, re-certification was required.

In January 2000, the Board approved a requested amendment to the study as follows:

In phase two of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits.

Results

Twenty-nine licensed pharmacists (15 at CSMC, 14 at LBMMC) participated in Part I of the study to obtain a baseline of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 at both) participated in the study. All forty-one successfully completed the didactic training, thirty-nine successfully completed the audits and became certified checkers, and two technicians did not complete the 3500 doses due to re-assignment in work area or resignation.

No technician was removed from the study due to inadequate performance in meeting the target accuracy rate of 99.8%. However, some technicians were removed from the list of certified checkers during the study period due to work reassignments or other non-study-related issues. The Board was notified of such changes in the bi-annual reports submitted.

Table 1 and Table 2 list the accuracy rates of pharmacist and technician checkers, respectively. The combined-institution (total) average accuracy rate for pharmacist checkers was 99.52%. In comparison, the combined-institution average accuracy rate for technicians during the certification process was 99.88%, which exceeded the minimum requirement of 99.8% to be a certified checker. As noted in Table 2, two technicians did not complete the certification process, since they did not complete audits for a total of 3500 doses; however, their data was included in the analysis since they completed the didactic training. No technician from either institution failed to meet the minimum accuracy requirement to be a certified checker.

With respect to monthly/quarterly audits of the certified technician checkers, all met the criteria to continue to serve as a certified checker. These audits were submitted to the Board in the bi-annual reports, and are summarized for CSMC and LBMMC in Tables 3 and 4, respectively.

There were no reports at either institution of any adverse events due to medication errors as a result of having technicians check the unit-dose cassettes.

Conclusion

Trained technicians met or exceeded the target rate of 99.8% average accuracy in checking unit-dose medication cassettes. Moreover, the technicians in this study had a slightly superior checking accuracy in comparison to the pharmacist checkers. Again, it should be emphasized that medication orders are checked by a pharmacist to ensure the accuracy and appropriateness of a prescriber's order before a technician fills or stocks a unit-dose medication cassette.

Table 1

Accuracy of Pharmacists Checking Unit-Dose Cassettes

Institution	No. of Pharmacists	No. of Doses	Mean Accuracy
CSMC	15	12,626	98.85 %
LBMCC	14	23,203	99.89 %
Total	29	35,829	99.52 %

Table 2

Accuracy of "Certified" Technicians Checking Unit-Dose Cassettes

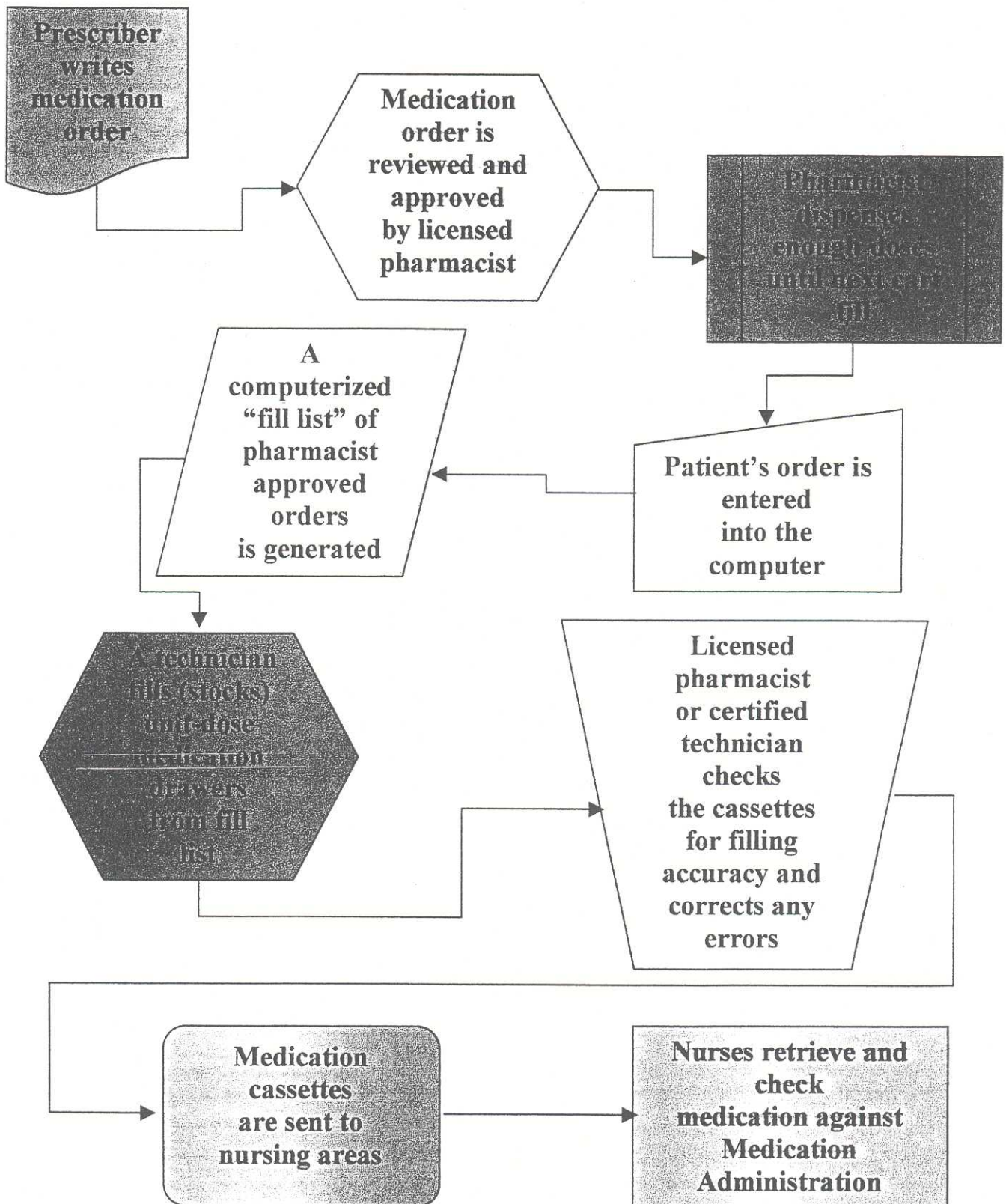
Institution	No. of Technicians	No. of Doses	Mean Accuracy
CSMC	25	106,744	99.88%
LBMCC	17 ^a	54,996	99.89%
Total	41 ^b	161,740	99.88%

^a Two technicians did not complete the 3500 dose requirement to become qualified.

^b One technician worked and participated for both institutions.

Diagram

The unit-dose distribution system employed by both CSMC and LBMMC.



*Medication Administration Records are based on pharmacist-verified orders.

Monthly/Quarterly Audits for CSMC

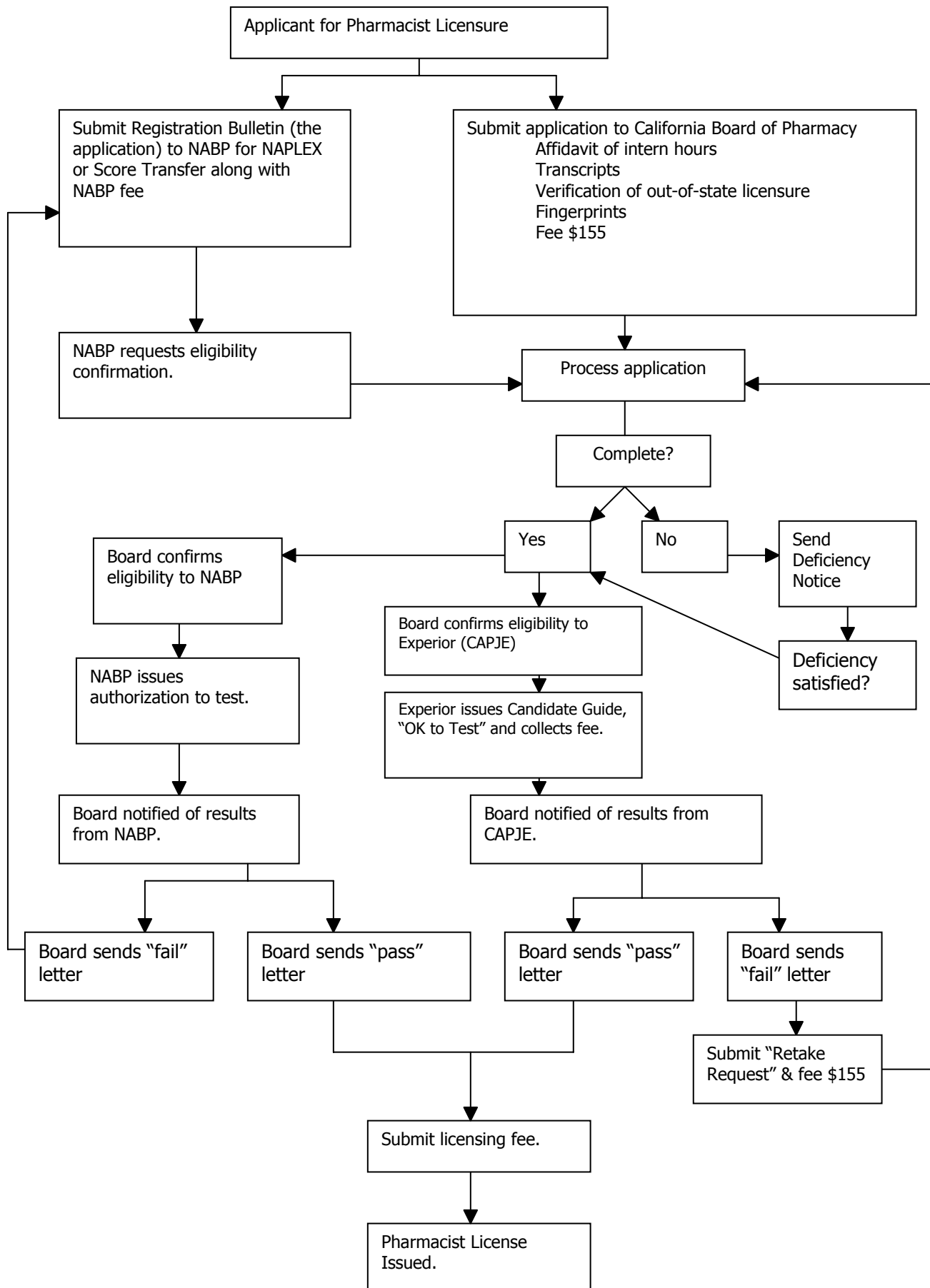
AVERAGE ACCURACY

Table 4

Monthly/Quarterly Audits for LBMIMC

CERTIFICATION				RECERTIFICATION AUDITS																			
No.	Last Name	First Name	Reg. #	Name Submitted	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00
1				OP report #2	inactive	from study	inactive	Passed	inactive	Passed	Passed	Passed	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
2				OP report #2	withdrawn	Passed	inactive	inactive	inactive	inactive	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	Passed	
3				OP report #2	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
4				OP report #2	Passed	Passed	inactive	inactive	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
5				JP report #3	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
6				JP report #3	Passed	inactive	inactive	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
7				JP report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
8				JP report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
9				JP report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	inactive	
10				JP report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
11				P report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
12				P report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
13				P report #3	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
14				P report #4	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
15				P report #4	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
16				P report #4	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
17				P report #5	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	
Average Accuracy Rate					99.9%	99.9%	99.8%	99.8%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	100.0%			99.9%		99.9%		99.9%

Attachment F



Becoming Licensed as a Pharmacist in California

Effective January 1, 2004, California will have a new examination program for applicants who seek to become licensed as pharmacists in California. These changes were made by SB 361 (Figueroa, Chapter 361, Statutes of 2003).

The examination process will be comprised of two parts:

1. Passing the North American Pharmacist Licensure Examination (or NAPLEX) which is prepared by the National Association of Boards of Pharmacy. For the score to be valid in California, this exam must be taken and passed after January 1, 2004.
2. Passing the California Pharmacist Jurisprudence Licensure Examination for California. This exam will be developed by the California State Board of Pharmacy and will be available sometime early in 2004; we believe after March 1, 2004. (Note: this exam is different than the Multistate Pharmacist Jurisprudence Examination administered by NABP.)

Both of these examinations will be given via a computer, and will be available for approved applicants to take the examination five days a week, and perhaps six days a week throughout the year.

The new exam structure replaces the board's prior written examination that was given twice a year. The board is **NOT** giving a January 2004 written examination. Instead, passing the two tests listed above will take the place of our former examination. As such, there is no November 2003 deadline to apply to take these examinations (as would have been required if the board continued to give its prior examination).

In order to give these two examinations, contracts must be in place. The California Board of Pharmacy is working to secure these contracts.

The contracts will specify various aspects of how applicants must apply to take the exams, where the exams will be given, deadlines and timelines for applications and other specifics related to the administration of the exams, and release of test scores. At this time, many of these details are not known.

The board believes that these contracts will be finalized in the next few months. The board's goal is to have the contracts in place so the exams can be given no later than March 2004. If so applicants who pass the exam will be eligible for licensure at the beginning of April 2004 – the same time that release of exam scores would have occurred had the board continued to give its prior exam.

After the contracts are in place, candidates will be able to take either of these examinations throughout the year at multiple locations.

Within several weeks, the board will have an application available online, which can be completed and submitted to the board. This is the first part in the application process where California will review your qualifications to take the pharmacist licensure examination.

The requirements to take the examination will remain the same. Specifically, to take the pharmacist licensure examination for California, you must:

1. Be at least 18 years of age
2. Be a graduate of a domestic school of pharmacy or be a graduate of a foreign school of pharmacy and have passed the Foreign Pharmacy Graduate Equivalency Examination.
3. Have completed at least 150 semester hours of collegiate credit, 90 of which must be from a school of pharmacy
4. Have earned at least a baccalaureate degree in a course of study devoted to pharmacy
5. Have 1,000 hours of approved pharmaceutical experience as a registered intern or one year of experience as a licensed pharmacist in another state.

If you have taken or qualified to take the California pharmacist licensure examination in the past, the board may still have your file. If you have already submitted an application for the January 2004 written examination or postponed taking the June 2003 written examination, the board will soon mail you an information packet detailing the application requirements. The board will apply your \$155 application fee to the application fee for the new examination.

If you failed the June 2003 California Licensure Examination, you will need to submit a new application (as stated above, this form will soon be available on the board's Web site).

If you have failed the California licensure exam four times, you are required to complete 16 units of remedial education in pharmacy coursework in an ACPE-approved school of pharmacy.

If you wish to take the NAPLEX exam before California has finalized the contract for the new exams, you may apply for licensure as a pharmacist in another state. All other states use the NAPLEX exam. If you do this, you must designate California as a score transfer state before you take the NAPLEX, AND you must take the NAPLEX after January 1, 2004. (Please

refer to the Score Transfer Bulletin available on the NABP website for more information.)

The NAPLEX/MPJE Examination Bulletin is available online (<http://www.nabp.net>). This manual will assist you in learning about the NAPLEX exam. The California Board of Pharmacy has no involvement with the development of the NAPLEX examination.

Some applicants may also seek to take the PreNAPLEX exam to assist in the test preparation for the NAPLEX. If so, contact the NABP Website for information (<http://www.nabp.net>).

The board is developing a Candidates' Guide for the California Pharmacist Jurisprudence Examination. This guide will be available from the board's Web site once it is complete.

A copy of the content outline for the California Pharmacist Jurisprudence Examination is already available from http://www.pharmacy.ca.gov/pdfs/exam_outline.pdf.

The board will provide additional information to this Web site as it becomes available. Please be patient. We recognize how important it is to provide application information to you, we are still finalizing details for the process.

Questions and Answers:

The board will provide answers to frequently asked questions at this area of our Web site.

Should you have questions regarding the new examinations, please send them to Debbie_Anderson@dca.ca.gov. While you will not receive a direct response to your e-mail inquiry, the board will answer those questions with broad applicability. Other, more specific questions will not be answered at this time because many details about the exam program will not be available until the contracting processes are complete.

Questions concerning a specific individual's eligibility or application will **NOT** be answered.

Q: I passed the NAPLEX already and I am licensed in another state, how can I reciprocate my license?

A: The law does not allow for reciprocation. You are required to take and pass both the NAPLEX and California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: When can I take the NAPLEX and California Pharmacist Jurisprudence Exam?

A: The law provides for acceptance of passing scores on the NAPLEX received after January 1, 2004. The board is currently developing the California Pharmacist Jurisprudence Examination. Please continue to check the Web site for information as to when the California Pharmacist Jurisprudence Examination will be available.

Q: Are the NAPLEX and California Pharmacist Jurisprudence Examination computerized and multiple-choice examinations?

A: Yes

Q: I have already submitted an application for the California January 2004 exam. What do I do?

A: The board will communicate to you in writing with further instructions as soon as procedures are finalized. This may be several months.

Q: When are the revised applications anticipated to be on your website?

A: The applications are currently under legal approval. The board anticipates the applications posted on this Web site in early December.

Q: If the board's applications won't be on the Web site until beginning to mid-November, how can I submit my application by the November 13, 2003 deadline?

A: The November 13, 2003, deadline will not apply to the NAPLEX or California Pharmacist Jurisprudence Examination. Because the board will no longer give its written examination, this deadline is no longer applicable.

Additional questions submitted to the board:

Q: When is the earliest date I can take the NAPLEX?

A: Applicants for California licensure must take and pass the NAPLEX exam after January 1, 2004. There are no exceptions.

Q: I graduate in January, but my transcripts won't be available until February. Can I take the NAPLEX prior to the board receiving my transcripts?

A: No, the board must receive your transcripts with the degree posted before the board will confirm your eligibility to NABP (which qualifies you to the NAPLEX for California).

Q: If I take the MPJE examination offered by the NABP, do I still have to take the California Jurisprudence Examination?

A: Yes. The MPJE examination offered by the NABP is a separate examination required by some states for licensure. It is not a requirement for licensure in California. Rather, applicants must pass the California Pharmacist Jurisprudence exam in addition to the NAPLEX to become licensed in California. As is stated above the application process for the California exam is not finalized.

Q: I am scheduled to take the NAPLEX examination in January 2004 for another state and would like to transfer my score to California. What are the procedures?

A: Score Transfers are completed by the NAPB. Please visit its Web site www.nabp.net for the specific requirements. Please be advised, however, that the board is still finalizing the contract with the NABP. As such, the NABP may decide not to accept applications for a score transfer to California until after the contract is signed.

Q: I took the NAPLEX examination in October 2003. Can I transfer this score?

A: No. To become licensed in California, you must take and pass the NAPLEX and the California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: Do I have to wait until March 2004 to take the NAPLEX examination?

A: No. The board will accept a passing score on the NAPLEX examination as long as the examination is taken and passed after January 1, 2004. The NABP will require you to transfer your score according to the NABP's score transfer procedure. (You must request a score transfer prior to taking the NAPLEX.)

Q: Is the California Specific Examination Content Outline posted on your Web site referring to the NAPLEX MPJE examination for California?

A: The content outline posted on the board's Web site is for the California Pharmacist Jurisprudence Examination. There is no NAPLEX MPJE examination required for applicants to become licensed in California. Rather an individual must take and pass the NAPLEX examination and the California Pharmacist Jurisprudence Examination after January 1, 2004.

Q: I heard that the NAPLEX examination is changing after January 1, 2004, and will be more difficult to pass. Is this true?

A: The NAPLEX examination is developed and administered by the NAPB. The board is not aware of any changes being made to this examination.

Q: What do I need to do if I want to take the NAPLEX examination for California?

A: You must submit an examination application to the California Board of Pharmacy and satisfy all of the requirements. You must also submit a "Registration Bulletin" with the NABP to take the NAPLEX.

Q: If I pass the NAPLEX examination but fail the California Pharmacist Jurisprudence examination, do I need to retake both exams or just the California Pharmacist Jurisprudence examination?

A: You will need to retake the California Pharmacist Jurisprudence examination only.

Q: I failed the California Board Examination four times and I am completing the 16 semester units required to reapply in California. At what point can I take the NAPLEX and California Pharmacist Jurisprudence examination?

A: You must complete the 16 semester units prior to reapplying in California.

Q: Your Web site states that the California Pharmacist Jurisprudence exam is different from the MPJE. Does this mean that you don't have to take an MPJE examination in California or is the California Pharmacist Jurisprudence examination taking the place of the MPJE?

A: The California Pharmacist Jurisprudence examination is required. This examination is different than the MPJE administered by the NABP.

Attachment G



LICENSING COMMITTEE

Meeting Summary

DATE: December 3, 2003

TIME: 9:00 a.m. – 12 noon

LOCATION: Ramada Inn Burbank Airport
2900 North San Fernando Blvd.
Burbank, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Ruth Conroy, Pharm.D.
John Tilley, R.Ph.
Richard Benson, Public Member

STAFF

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Paul Riches, Legislation Manager

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:00 a.m. He recognized newly appointed committee member Richard Benson.

Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Specific Examination

Assistant Executive Officer Virginia Herold reported that staff has been working diligently to assure that the new examination structure is in place as soon as possible. Staff is in the process of negotiating the contracts for the NAPLEX and the California Pharmacist Jurisprudence Examination. The goal is to be able to issue licenses to pharmacists who have taken (and passed) the new examinations by the end of March 2004. This would be the same time as when the board would have been able to license pharmacists had they taken the board's prior exam.

The intent is for applicants who will take the NAPLEX after January 1, 2004, to have that score be available to California. Applicants must designate California as a score transfer state before they actually take the examination.

Ms. Herold also reported that the board would be able to administer the California Pharmacist Jurisprudence Examination via computer terminals in March 2004. The board will use the examination vendor under contract with the Department of Consumer Affairs for this portion of the examination instead of the NABP. The Competency Committee has developed a sufficient item bank of test questions for the new content outline for the examination, a significant task that required monthly meetings since August. The examination items are ready. The committee was given a flow chart for the new examination process. Also, information about the examination was added to the board's Web site and it is updated periodically. The committee was given the most recent update.

Report on the Changes to the Pharmacy Technician Program

Ms. Harris reported that starting January 1, 2004, there will be changes to the licensure requirements for applicants seeking registration as pharmacy technicians in California. These changes were the result of SB 361 (Figueroa, Chapter 361, Statutes of 2003).

Specifically, changes in Business & Professions Code section 4202 (a) alter the qualifying methods an applicant must satisfy to become registered. After January 1, 2004, to be issued a technician registration, an applicant must satisfy one of the following criteria:

- Obtain an associate's degree in pharmacy technology;
- Complete a course of training specified by the board (this is 240 hours of theoretical and practical training provided by a technician training school or by an employer);
- Be a graduate of a school of pharmacy accredited by the ACPE; or
- Be certified by the Pharmacy Technician Certification Board (PTCB).

Ms. Harris stated that information regarding these changes is available on the board's Web site. Also on the Web site is information on the associate's degree program and the PTCB examination. An article will also be included in the January 2004 issue of *The Script*. Staff is working with the department's legal counsel to finalize the new applications that should be available within the next few weeks.

It was reported that this is also an opportunity to streamline the application process because the revised applications not only reflect changes in law, but also should reduce the processing time for pharmacy technician applications. It is expected that these changes should significantly decrease the number of applications that are received with deficiencies.

Implementation of SB 490 (Alpert) Chapter 651 – Development of Statewide Protocol for Pharmacists to Dispense Emergency Contraception

Paul Riches reported that Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the

Board of Pharmacy and the Medical Board of California. Prior legislation (Senate Bill 1196, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber.

Staff has drafted the attached draft protocol for the committee's consideration. The draft protocol synthesizes elements from protocols submitted by the Pharmacy Access Partnership and the American College of Obstetricians and Gynecologists. Staff also reviewed protocols from the states of New Mexico and Washington and a sample protocol employed by pharmacists under the existing protocol requirements.

The draft protocol was drafted with the intent to keep the protocol simple and to comply with the statutory requirements established by Senate Bill 490. Both the Board of Pharmacy and the Medical Board of California must approve the protocol. The Medical Board of California is awaiting Board of Pharmacy action before considering the protocol.

The therapy of emergency contraception was discussed. The draft protocol has the therapy as two doses administered 12 hours apart within 72 hours of engaging in unprotected sex. However, it was noted that recent studies indicate that emergency contraception drug therapy remains substantially effective up to 120 hours (5 days) after unprotected sex and one emergency contraceptive product (Plan B) can be administered in a single dose. While the efficacy of emergency contraception declines over time, it remains approximately 80% effective when taken within 120 hours (5 days). The newer timing and dosing regimens would expand access to emergency contraception and the single dosing of Plan B would greatly aid in patient compliance with the therapy. The studies support no increased risk or side effects to the longer time period or the altered dosing regimen. It was stated that the American College of Obstetricians and Gynecologists has not reviewed the revised timing and dosing issues.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed statewide protocol with the request that the board consider modifying the protocol to include the Plan B therapy of a single dose within 5 days. The committee also requested that staff discuss this recommendation with the Medical Board of California.

Review of the Program Requirements for Intern Pharmacists (CCR, title 16, sections 1727 and 1728)

Ms. Harris reported that one of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's Web site. She stated that the Licensing Committee first discussed this issue at its meeting in June. While no written comments were received in advance of that meeting, the issue was discussed and it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052.

For the September Licensing Committee meeting, Dr. Hiura invited the deans from the

California schools of pharmacy to attend and requested that they bring program modifications for the committee's consideration. During the meeting, more recommendations were provided. Some of the suggestions were: updating the experience areas to include the detection and resolution of drug related problems and disease management; establishing minimum standards (that the board could enforce) for the pharmacy site using the residency program as a model, having the Competency Committee perform a comprehensive review of the intern program and authorizing the pharmacist to supervise two interns.

Based on these discussions, staff reviewed the intern program requirements and drafted modifications. First and foremost, it was recommended that the board consider placing the intern requirements into statute. Currently, all of the intern requirements are in regulation and it is more appropriate that they be in statute. Therefore, the proposal was written as statutory language and the program requirements updated accordingly. The changes included the following: a ratio of two interns to one pharmacist (this is consistent with current board policy), the requirement that the pharmaceutical experience comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education, and the elimination of the extension provision for the intern permit and the definition of a preceptor.

There was discussion regarding proposed Business and Professions section 4208(c) which states that an intern pharmacist license cannot be issued to a person who has failed the pharmacist examination four or more times or to a person who has previously held an intern pharmacist license. The concern was that this section prevents a person who has failed the examination four times but who has returned to school (as required by law) to take the additional 16 units of education in order to re-qualify for the examination would not be eligible for an intern permit. In this situation, the person would not be able to maintain his/her proficiency as an intern while going to school. However, it was noted that the current regulation does not allow an intern a registration after failing the examination three times.

It was pointed out that this section would also prohibit the board from requiring that a "revoked" pharmacist work as an intern as part of the decision to "reinstate" the pharmacist's license. Usually when the board reinstates a pharmacist license that has been revoked, the board will order that the pharmacist serve a probationary period with the standard terms and conditions of probation. Because the revoked pharmacist has been out of practice for at least three years, the board usually will require that the pharmacist practice as an intern first.

It was also noted that Business and Professions Code section 4209(b) should be clarified because many interns are confused as to who must sign the intern affidavit and some interns believe that the pharmacist supervising the intern at that moment in time can only sign the form attesting to the experience.

The committee recommended that the board approve the proposed statutory changes with the clarifications as discussed.

Department of Health Services and Board of Pharmacy Workgroup on Compounding

Ms. Harris stated that at the March 2004 meeting, the Licensing Committee agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

The Licensing Committee agreed to establish a workgroup and to work on the project upon completion of its review of Pharmaceutical Benefit Managers (PBMs) and was added as a committee strategic objective.

Dr. Hiura reported that since the PBM review was completed, it was time to form the new compounding workgroup. He stated that the meetings would be public meetings with all interested parties invited to attend. He recommended Board Members John Tilley and Ken Schell participate as the board representatives and requested that Supervising Inspector Dennis Ming serve as well. It is anticipated that the meetings would be held in Sacramento, around February 2004.

The committee was given correspondence from John Cronin on behalf of his clients who had identified some issues that they would like addressed. The committee was also given the testimony before a U.S. committee regarding drug compounding by pharmacies.

Status Report on the Application Process for Security Printers of Controlled Substance Prescription Documents

Ms. Harris reported that Senate Bill 151 requires the Board of Pharmacy, in coordination with the Department of Justice (DOJ), to approve security printers prior to the production of secure prescription forms for controlled substances. Staff has drafted procedures, the application forms and is in the process of coordinating the review and approval process with the DOJ.

The goal is to have a final draft of the application packet ready for review by Legal in mid-December so that the application packet can be available on the board's Web site by the first of January.

10th Report from the UCSF, School of Pharmacy Sponsored Study on the Evaluation of Pharmacy Technicians in a Unit-Dose Drug Distribution System

Ms. Harris reported that in May 1998 the Board of Pharmacy approved a study on the evaluation of pharmacy technicians in a unit-dose distribution system. The UCSF School of Pharmacy sponsored the study in conjunction with Long Beach Memorial Medical Center (LBMMC) and Cedars Sinai Medical Center (CSMC). The study will end on December 31, 2003.

Ms. Harris provided a background on the study. She stated that the Board of Pharmacy originally granted that waiver from May 1998 until November 1, 2000. The waiver was granted

pursuant to California Code of Regulation section 1731. Because of the delay in starting the study, the board extended the waiver until February 2001, and requested that UCSF, LBMMC and CSMC present the final report at its January 2001 meeting. When the final report was presented, the board agreed to extend the study another two years so that either regulation or legislation could be pursued to authorize the use of pharmacy technicians as allowed by the study. Because legislation was not introduced until last year, the sponsors requested another extension, which the board granted until the end of this year.

The Licensing Committee requested that a final report be presented to the board at its next meeting.

Meeting Dates for 2004

The Licensing Committee set its meeting dates for 2004. They are: March 3rd, June 9th, September 22nd, and December 1st. The members requested that the meetings start at 9:30 a.m. and be held either in Oakland or Burbank.

Adjournment

Licensing Committee Chair Clarence Hiura adjourned the meeting at 11:45 a.m.

Attachment H

Licensing Committee
2003-2004
Second Quarter Report
July 1, 2003 – December 31, 2003

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2005.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system is in the testing phase and should be fully implemented by November 1, 2003. Therefore, some of the information are estimates and will be notated with an asterisk.

Tasks: **1. Review 100 percent of all applications within 7 working days of receipt.**

Note: Pharmacists examination applications are not being processed because of the changes outlined in SB 361. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:		Average Days to Process:	
	Q1	Q2	Q1	Q2
Pharmacy Intern	689	424*	3	7-10
Pharmacy Technicians	1848	1220*	15	13
Foreign Graduates	111	48*	n/a	n/a
Pharmacies	131	88	7	13
Non-Resident Pharmacy	19	12	23	25
Wholesaler	21	25	7	8
Veterinary Drug Retailer	1	0	n/a	33
Exemptee	159	97	6	4
Out-of-State Distributor	20	14	15	18
Clinics	48	48	8	9
Hypo Needle & Syringe	18	12	5	17
Sterile Compounding	36	23	7	7

* denotes October and November 2003 information available at time of report development.

2. Process 100 percent of all deficiency documents within 3 working days of receipt.

Average days to process deficiency:

	Q1	Q2
Pharmacist	3	3
Pharmacy Intern	3	7-10
Pharmacy Technician	14	17
Foreign Graduate	n/a	n/a
Pharmacies	19	15
Non-Resident Pharmacy	25	44
Wholesaler	12	8
Veterinary Drug Retailer	n/a	7
Exemptee	38	38
Out-of-State Distributor	12	11
Clinics	19	12
Hypo Needle & Syringe	7	2

3. Make a licensing decision within 3 working days after all deficiencies are corrected.

Average days to issue license:

	Q1	Q2
Pharmacist	1	1
Pharmacy Intern	1	1
Pharmacy Technician	10	10
Foreign Graduate	n/a	n/a
Pharmacies	14	16
Non-Resident Pharmacy	64	13
Wholesaler	4	3
Veterinary Drug Retailer	n/a	1
Exemptee	1	27
Out-of-State Distributor	9	2
Clinics	12	6
Hypo Needle & Syringe	6	2

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Q1	Q2
Pharmacist	599	125
Pharmacy Intern	565	517
Pharmacy Technician	2221	2007
Foreign Graduate	n/a	n/a
Pharmacies	147	99
Non-Resident Pharmacy	21	18
Wholesaler	43	20
Veterinary Drug Retailer	0	1
Exemptee	152	82
Out-of-State Distributor	22	17
Clinics	45	52
Hypo Needle & Syringe	11	9

5. Withdrawn licenses to applicants not meeting board requirements.

	Q1	Q2
Pharmacy Technician	10	5
Pharmacies	4	5
Non-Resident Pharmacy	2	3
Clinics	0	10

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**

Measure: **Number of implemented changes.**

Tasks: **1. Review Pharmacist Intern Program.**

09/03 *Discussed at Licensing Committee Meeting. No recommendations were made. Will revise intern reporting affidavits.*

12/03 *Discussed proposed statutory changes and Licensing Committee recommended board approval.*

2. Implement changes to the Pharmacy Technician Program.

a. Use PTCB as a qualifying method for registration.

b. Eliminate clerk-typist from pharmacist supervisory ratio.

- c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.

9/03 Governor signed SB 361. New changes will be implemented 11/04. Regulation changes are proposed to the board. Application forms have been revised.

10/03 Board approved proposed regulation changes. Regulation proposal pending with Legislative/Regulation Committee.

12/03 New application forms made available on website.

3. Administer a pharmacist licensure exam more than twice a year.

09/03 Governor signed SB 361 to implement NAPLEX and California specific exam to be administered quarterly via computer. The Licensing Committee recommended regulation changes to implement new examination program.

10/03 Board approved proposed regulation changes.

12/03 Proposed regulation changes are pending with the Legislative/Regulation Committee.

4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.

09/03 Developed content outline for California specific exam and made available on board's website. Additional test questions identified by Competency Committee for inclusion in Candidate's Review Guide.

12/03 Worked on new Candidate Review Guide for the California specific examination.

12/03 Revised application and instruction forms.

12/03 Finalized contracts for the new examinations.

5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.

6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.

8/03 *Competency Committee met for two days and finalized content outline. Reviewed question bank.*

9/03 *Competency Committee met for two days and developed questions.*

10/03 *Competency Committee met for two days and developed questions.*

11/03 *Competency Committee met for three days and developed questions.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

9/03 *Reported that 126 sterile compounding licenses have been issued since July 1.*

8. Issue temporary permits whenever change of ownership occurs.

9/03 *1st Quarter - 24 temporary permits issued.*

1/04 *2nd Quarter – 12 temporary permits issued.*

9. Establish means for licensee to renew permits on line.

8/03 *NABP is establishing a program that will allow states to establish criteria for licenses to be renewed on line through NABP. The board has requested Legal Affairs to review this as a possible option for the board.*

10. Implement Changes to Facilities Licensure Requirements

9/03 *Proposed statutory changes to the licensure requirements for wholesale facilities. Recommended board support requirements.*

9/03 *Proposed statutory changes that would clarify the licensure requirements for facilities. Would prohibit facilities from being located in a personal residence and clarifies that the board issues a permit at one premise and is a separate operation. Recommend board support.*

10/03 *Board approved proposed statutory changes for wholesale facilities and other licensure requirements.*

12/03 *Statutory proposals are pending with the Legislative/Regulation Committee.*

11. Review the Ownership of Pharmacies (LLC)

10/03 *Board determined that a Limited Liability Company can own a pharmacy.*

Objective 2.3:	Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.
Measure:	Number of public policy initiatives evaluated.
Tasks:	<p>1. Explore the need to regulate pharmacy benefit managers.</p> <p><i>9/11/03 Ad Hoc Committee held 3rd meeting. Requested completion of Sunrise Questionnaire. Recommended that the board not take action.</i></p> <p><i>10/03 Board agreed with recommendation, but will continue to "watch" the issue.</i></p> <p>2. Explore the need to regulate drugs labeled for "veterinary use only."</p> <p><i>9/03 SB 175 was introduced and signed (Chapter 250, Statutes 2003).</i></p> <p>3. Explore the importation of drugs from foreign countries.</p> <p><i>7/03 Discussed at July Enforcement Committee and board meetings.</i></p> <p><i>9/03 Discussed at September Enforcement Committee.</i></p> <p><i>10/03 Discussed at October Board meeting.</i></p> <p><i>12/03 Discussed at December Enforcement Committee meeting.</i></p> <p>4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.</p> <p><i>9/03 Legislation and Regulation Committee held informational hearing – Completed.</i></p> <p>5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding</p> <p><i>12/03 Licensing Committee requested participation of Board Members John Tilley, Ken Schell and Supervising Inspector Dennis Ming to participate in workgroup.</i></p>
Objective 2.4:	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.
Measure:	Percentage of cashiered application and renewal fees within 2 working days.
Tasks:	<p>1. Cashier application fees.</p> <p><i>9/03 1st Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p>

<i>1/04</i>	<i>2nd Quarter - The average processing time for processing new application fees is 2-3 working days.</i>
2. Cashier renewal fees.	
<i>9/03</i>	<i>The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.</i>
<i>9/03</i>	<i>1st Quarter - Average processing time for central cashiering is 2-3 weeks.</i>
<i>1/04</i>	<i>2nd Quarter - Average processing time for central cashiering is 2-3 weeks.</i>

Objective 2.5:	Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.
Measure:	Percentage response for verifying licensing information within 5 working days.
Tasks:	1. Respond to requests for licensing verification.
<i>9/03</i>	<i>1st Quarter – Processed 261 license verifications.</i>
<i>1/04</i>	<i>2nd Quarter – Processed 178 license verifications.</i>
Objective 2.6:	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	1. Make address and name changes.
<i>9/03</i>	<i>1st Quarter – Processed 1,994 address changes.</i>
<i>1/04</i>	<i>2nd Quarter – Processed 2,679 address changes.</i>
	2. Process discontinuance of businesses forms and related components.
<i>9/03</i>	<i>1st Quarter – Processed 34 discontinuance- of-business forms. Processing time is 40 days.</i>
<i>1/04</i>	<i>2nd Quarter - Processed 26 discontinuance- of-business forms. Processing time is 7 days.</i>
	3. Process changes in pharmacist-in-charge and exemptee-in-charge.
<i>9/03</i>	<i>1st Quarter – Processed 539 pharmacist-in-charge changes. Average</i>

processing time is 130 days. Processed 3 exemptee-in-charge changes. The average processing time is 14 days.

1/04 *2nd Quarter – Processed 225 pharmacist-in-charge changes. Average processing time is 14 days. Processed 6 exemptee-in-charge changes. The average processing time is 8 days.*

4. Process off-site storage applications.

9/03 *Processed 43 off-site storage applications.*

5. Process change-of-permit applications.

9/03 *1st Quarter – Processed 185 applications. Average processing time is 130 days.*

1/04 *2nd Quarter – Processed 71 applications. Average processing time is 12 days.*